

EDA PSUR Supplementary List dated 06-06-2024 (Effective from 06-06-2024)

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

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	29/08/2024	07/11/2024		07/11/2025	
Dactaravir	Sofosbuvir	3 years	05/12/2024	05/03/2025			
Lamivudine	Lamivudine from removed entries in EURD list	13 years	01/01/2025	01/04/2025			
Mitiglinide	Mitiglinide from removed entries in EURD list	13 years	01/01/2025	01/04/2025			
Dalfampridine	Fampridine	5 years	21/01/2028	20/04/2028			
Omeprazole + Sodium bi-carbonate	Omeprazole	5 years	15/04/2027	14/07/2027		09/07/2025	
Bupivacaine Hydrochloride + Fentanyl (Injection)	Fentanyl (transdermal patches, solution for injection -nationally authorised product only)	1 year	30/04/2024	09/07/2024			
Edaravone	Japan only	1 year	12/12/2023	20/02/2024		20/02/2025	
Loxoprofen	Ibuprofen, Ibuprofen lysine (not indicated in ductus arteriosus), Ibuprofen / caffeine	3 years	18/02/2026	19/05/2026			
Vilazodone	Trazodone	6 years	03/08/2023	01/11/2023		01/11/2029	
Gentamicin + Miconazole + Mometasone	Mometasone	5 years	22/05/2028	20/08/2028			
Moxifloxacin HCL+ Dexamethasone (Ophthalmic)	Levofloxacin + Dexamethasone (ocular use)	3 years	12/06/2025	10/09/2025			
Alcathaine (Ophthalmic)	As the Innovator + FDA only	1 year	27/07/2024	05/10/2024		05/10/2025	
Carboxymethyl Cellulose + Glycerin (Ophthalmic)	Carmellose (eye preparation)	13 years	01/10/2025	30/12/2025			
Dexamethasone + Chlorpheniramine	Dexamethasone + Diphenhydramine hydrochloride	13 years	01/01/2025	01/04/2025			
Gatifloxacin sesquihydrate (Ophthalmic)	Oloxacain (Topical use)	3 years	16/04/2024	15/07/2024			
Mimodronic acid	risedronate, risedronate, risedronate/calcium/colecalciferol	5 years	31/03/2026	29/06/2024			
Ribamipide	Ribamipide from removed entries in EURD list	13 years	01/01/2025	01/04/2025			
Guaifenesin + Osometemazine + Carbocisteine	Carbocisteine	13 years	14/09/2025	13/12/2025			
Batenafine	Terbinafine	3 years	30/09/2025	29/12/2025			
Ritigabine	Retabamine from removed entries in EURD list	1 year	28/09/2024	07/12/2024		07/12/2025	
Ferrous sulphate + Folic acid + Riboflavin + Pyridoxine HCl + Zinc sulfate + Nicotinamide + Ascorbic acid + Thiamine	Ascorbic acid + Biotin + Cyanocobalamin + Folic acid + Nicotinamide + Pantothenic acid + Pyridoxine hydrochloride + Riboflavin + Thiamine	10 years	27/09/2027	26/12/2027			
Neomycin sulfate + Nystatin + Triamcinolone acetone + Gramicidin	Neomycin sulfate + Nystatin + Triamcinolone acetone	6 years	02/12/2029	01/03/2030			
Aluminium hydroxide gel + Magnesium hydroxide + Docusate	Aluminium hydroxide gel + Dimeticone + Magnesium hydroxide	13 years	01/01/2025	01/04/2025			
Glycerin + Carboxymethylcellulose + Sodium Hyaluronate	Glycerol	13 years	01/01/2025	01/04/2025			
Ascorbic acid + Zinc	Ascorbic acid	13 years	25/02/2025	26/05/2025			
Pipazethate	Non reference	1 year	01/05/2024	10/07/2024		10/07/2025	
Favipiravir	Remdesivir	1 year	06/05/2024	15/07/2024	06/05/2025	15/07/2025	
Artesunate + Sulfamethoxyprazine + Pyrimethamine	Artesunate	1 year	22/12/2023	01/03/2024	22/06/2024	31/08/2024	
Naphazoline HCL + Pheniramine maleate	Naphazoline	12 years	31/07/2024	29/10/2024			
Sulfamethoxazole + Trimethoprim + light Kaolin + Pectin	Sulfamethoxazole + Trimethoprim	8 years	31/03/2027	29/06/2027			
Aluminium hydroxide gel + Magnesium hydroxide + Simeticone	Aluminium oxide + Magnesium hydroxide + Simeticone	13 years	01/01/2025	01/04/2025			
Ethanolamine Oleic acid	Ethanolamine	13 years	01/01/2025	01/04/2025			
Metformin Hydrochloride + Repaglinide	Metformin	3 years	01/04/2024	30/06/2024			
Metoclopramide + Pyridoxine	Metoclopramide	3 years	17/11/2024	15/02/2025			
Levodopa + Entacapone	Carbidopa + Entacapone + levodopa	3 years	17/10/2024	15/01/2025			
Penicilast	Japan only	1 year	30/04/2024	09/07/2024		29/07/2025	
Tolmetin sodium	Acetofenac	5 years	31/03/2028	29/06/2028			
Amiloride + Pivalbucic	Amiloride	6 years	06/06/2029	11/01/2029			next DLP updated on 06/06/2024
Eplerone	Tolperisone	2 years	01/06/2024	30/08/2024			

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Colour Indicators								
Blue	Recently added active ingredients & active ingredient combinations							
Yellow	PSUR Frequency and DLP updated							
Orange	PSUR Frequency updated							
Green	Highly important							
Phenylephrine Hydrochloride + Hypermellose (Ophthalmic Solution)	Phenylephrine (Ophthalmic formulations)	5 years	01/01/2025	01/04/2025				
Carbazochrome + Troxerutin	Carbazochrome	13 years	19/03/2025	17/06/2025				
Mefenorexate	Japan only	1 year	30/04/2024	09/07/2024			09/07/2025	
Acetaminophen + Paracetamol + Pseudoephedrine	Paracetamol + Pseudoephedrine	5 years	28/06/2025	26/09/2025				next DLP updated on (06/06/2024)
Ursodeoxycholic acid + Silymarin	Ursodeoxycholic acid, tauroursodeoxycholic acid	10 years	30/11/2026	28/02/2027				
Nitazoxanide	FDA only	1 year	29/07/2024	07/10/2024				
Imeglimin Hydrochloride	Japan only	1 year	30/04/2024	09/07/2024				07/10/2025
Calcitriol	Calcitriol	3 years	18/03/2024	08/06/2024				09/07/2025
Molnupiravir	Newly authorized active ingredient	6 months	17/06/2024	26/08/2024			17/12/2025	26/02/2025
Vitamin B1 + Vitamin B2 + Vitamin B6 + Nicotinamide + Dexpanthenol	Caffeine + Dexpanthenol+ Nicotinamide + Pyridoxine + Riboflavin + Thiamin	13 years	01/01/2025	01/04/2025				
Vitamin B1 + Vitamin B2 + Vitamin B6 + Vitamin B12 + Nicotinamide + Calcium D-pantothenate + Ascorbic acid + Folic acid + Calcium phosphate + Ferrrous 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				
Guaifenesin + Terpine + cineol + sodium benzoate	guaifensin /herbal extracts	13 years	01/01/2025	01/04/2025				
Cefdinir	Cefotaxime	3 years	18/12/2024	18/03/2025				
Sodium Chloride + Sodium Bicarbonate + Borax	Sodium Chloride	13 years	24/11/2025	22/02/2026				
Benzoic acid + Salicylic acid (Topical)	Salicylic acid (Topical use)	6 years	02/12/2023	01/03/2024				
Paracetamol + Pamabrom	Paracetamol + Orphenadrine citrate	13 years	01/01/2025	01/04/2025				
Chlorphenoxamine hydrochloride + Caffeine	Chlorphenoxamine	9 years	17/05/2027	15/08/2027				
Phenylephrine Hydrochloride + Cyclopentolate Hydrochloride (Ophthalmic Solution)	Phenylephrine (Ophthalmic formulations)	5 years	01/01/2025	01/04/2025				
Amoxicillin + Flucloxacillin	Amoxicillin	5 years	07/03/2027	05/06/2027				
Vonoprazan	Japan only	1 year	23/08/2024	01/11/2024				01/11/2025
Doripenem	Meropenem	3 years	31/08/2024	29/11/2024				
Ammodafinil	Misofinil	3 years	31/08/2026	29/11/2026				PSUR Frequency and DLP updated
Cildinium Bromide + Chloridazepoxide	Acidinium Bromide	1 year	20/07/2024	28/09/2024				28/09/2025
Oxytetracycline hydrochloride + Polymyxin b	Hydrocortisone acetate + Oxytetracycline hydrochloride + Polymyxin b	13 years	01/01/2025	01/04/2025				
Telmisartan + Amlodipine + Hydrochlorothiazide	Olnesartan + Amlodipine + Hydrochlorothiazide	5 years	24/04/2027	23/07/2027				
Chlorzoxazone + Paracetamol	Chlorzoxazone	13 years	28/06/2025	26/09/2025				
Silver sulfadiazine + Chlorhexidine	Silver sulfadiazine	5 years	15/09/2025	14/12/2025				
Diclofenac	Diclofenac	13 years	01/01/2025	01/04/2025				
Dexamethasone + Dexamethasone	Dexamethasone + Hydrocortisone	5 years	01/11/2026	30/01/2027				
Dextromethorphan + Chlorpheniramine	Dextromethorphan	1 year	01/11/2026	03/01/2025				03/01/2026
Dibucaine + Metronidazole	Non reference	1 year	25/10/2024	23/05/2025				
Cyanocobalamin - Tannin complex in Aluminium monostearate	Cyanocobalamin	13 years	22/02/2025	23/05/2025				
Magnesium hydroxide + Light Liquid Paraffin	Magnesium hydroxide	5 years	31/10/2026	29/01/2027				
Nonoxonyl-9	Non reference	1 year	01/05/2024	10/07/2024				10/07/2025
Revefenacin	Acidinium bromide	1 year	20/07/2024	28/09/2024				28/09/2025
Clofedanol	Pentoxifylline	5 years	31/12/2023	30/03/2024				
Paracetamol + Guaifenesin + Phenylephrine + Dextromethorphan	Dextromethorphan + Paracetamol + Phenylephrine	6 years	03/11/2023	01/02/2024				
Chloramphenicol + Dexamethasone + Tetryzoline	Dexamethasone (Apart from centrally authorized products)	5 years	31/01/2026	01/05/2026				
Fluorometholone + Tetrahydrozoline	Fluorometholone	13 years	31/07/2025	29/10/2025				
Bifacalcin	Prednisolone	6 years	08/03/2029	11/01/2029				next DLP updated on (06/06/2024)
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				
Carvedilol + Hydrochlorothiazide	Carvedilol	5 years	17/04/2027	16/07/2027				
Hydroquinone + Tretinoin + Hydrocortisone (Topical)	Tretinoin (topical formulations)	5 years	31/08/2027	29/11/2027				
Guaifacil + Phloclodine	Non reference	1 year	29/05/2024	27/08/2024				27/08/2025
Ofloxacin + Dexamethasone	Levofloxacin + Dexamethasone (ocular use)	3 year	12/06/2025	10/09/2025				
Tadalafil + Finasteride	FDA only	1 year	31/08/2024	09/11/2024				09/11/2025
Terecnamole	Terecnamole from removed entries in EURD list	13 years	01/01/2025	01/04/2025				
Chlorzoxazone + Ketoprofen	ketoprofen (all formulations except topical)	5 years	23/01/2027	23/04/2027				
Povidone Iodine+ Sucrose	02/01/2024	7 years	02/01/2024	01/04/2024				
Acetylglucine	Acetylglucine from removed entries in EURD list	13 years	01/01/2025	01/04/2025				
Isotretinoin (Topical)	tretinoin (Topical formulations)	5 years	31/08/2027	29/11/2027				

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Blue	PSUR Frequency and DLP updated					
Yellow	PSUR Frequency updated					
Orange	PSUR Frequency updated					
Monocyclic						
Mometasone furoate + Formoterol	Mometasone	5 years	22/05/2028	20/08/2028		
Doxercalciferol	Doxercalciferol from removed entries in EURD list	13 years	01/01/2025	01/04/2025		
Paracetamol + Pseudoephedrine + Guaifenesin	Non reference	1 year	09/09/2024	18/11/2024		18/11/2025
Retapamulin						
Retapamulin	Retapamulin from removed entries in EURD list	3 years	11/04/2026	10/07/2026		
Filbanerlin	FDA only	1 year	09/09/2024	18/11/2024		18/11/2025
Ibuprofen + Methocarbamol	Ibuprofen, Ibuprofen lysine (not indicated in ductus arteriosus), Ibuprofen / caffeine	3 years	18/02/2026	19/05/2026		
Beta - Sitosterol						
Cefotetan Disodium	Second Generation Cephalosporins (cefprozil)	13 years	01/01/2025	01/04/2025		
Acetylcholine piperazine	Pharmacovigilance committee decision	5 years	22/12/2027	22/03/2028		
Atenolol + Amlodipine + Chlorzaldone	Atenolol + Chlorzaldone	1 year	30/09/2024	09/12/2024		09/12/2025
Metaxalone	Metaxalone from removed entries in EURD list	5 years	09/09/2024	08/12/2024		
Amylocaine Hydrochloride + Benzocaine + Hamamelis Dry Extract (5% Tannins) + Zinc Oxide + Aesculus Dry Extract	Non reference	13 years	01/01/2025	01/04/2025		
Selenium + Manganese Sulphate monohydrate + Vit.E + Vit.C + Beta Carotene + Zinc Sulphate monohydrate + Cu Sulphate Monohydrate	Selenium	1 year	15/10/2024	24/12/2024		24/12/2025
Vit.B1 + Vit.B2 + Vit.B6 + Folic acid + Calcium D Pantothenate + Vit.C + Zinc	ascorbic acid /biotin/cyanocobalamin/Folic acid/Nicotinamide/Pantothenic acid/ Pyridoxine hydrochloride/Riboflavin/Thiamine	8 years	01/12/2026	01/03/2027		
Vit.B12 + Nicotinamide + Biotin + L-Carnitine		10 years	27/09/2027	26/12/2027		
Acetylsalicylic acid + Magnesium carbonate + Aluminium glycinate	Japan only	2 years	01/02/2025	02/05/2025		
Theophylline + Ambroxol + Guaifenesin	Non reference	3 years	27/07/2026	25/10/2026		
Tetrahydrozoline (Tetryzoline) + Zinc Sulphate	Tetryzoline	13 years	01/01/2025	01/04/2025		
Terbutaline + Bromohexine HCL + Guaifenesin + Menthol	Bromhexine	3 years	30/09/2025	29/12/2025		
Bromhexine + Guaifenesin + Salbutamol	salbutamol	3 years	31/01/2026	01/05/2026		
Tiemonium Methyl Sulphate	Pharmacovigilance committee decision	5 years	01/02/2028	02/05/2028		
Magnesium oxide +Magnesium Gluconate	Magnesium oxide	13 years	30/06/2025	28/09/2025		
Natural calcium carbonate from oyster shell eq. to calcium + Vitamin D3+ Sodium fluoride	Sodium fluoride	5 years	13/11/2027	11/02/2028		
Lignocaine HCL + Clove oil + Geranium oil	lidocaine (topical use)	8 years	30/09/2028	29/12/2028		
L-Carnitine L-tartrate + Zinc gluconate	Carnitine	13 years	01/09/2025	30/11/2025		
Biotin + Alpha lipoic acid	Biotin	7 years	01/01/2026	01/04/2026		
Vitamin C + Vitamin B12 + L-lysine HCL + Ferrus 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		
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		
Magnesium carbonate + Citric acid	citric acid /magnesium /sodium, citric acid anhydrous / light magnesium oxide / sodium picosulfate	13 years	01/01/2025	01/04/2025		
Codcine + Pseudoephedrine + Triprolidine	Pseudoephedrine + Triprolidine	3 years	31/12/2023	30/03/2024		
Brompheniramine maleate + Paracetamol + Pseudoephedrine Hydrochloride	Chlorphenamine + Paracetamol + Pseudoephedrine	10 years	03/05/2035	01/08/2035		PSUR Frequency and DLP updated
Glucose anhydrous + Sodium Chloride + Potassium chloride + Sodium Lactate	Glucose (apart from glucose-1- 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	09/02/2034	12/01/2034		PSUR Frequency and DLP updated
Diosmin + Hesperidin + Ascorbic acid	Diosmin / hesperidin, ascorbic acid / dry Rosus extract titrated in steric heterosides/ Hesperidin methyl chalcone	13 years	01/01/2025	01/04/2025		
Cefoperazone	Pharmacovigilance committee decision	3 years	11/01/2024	11/04/2024		
Cefoperazone + Sulbactam	Pharmacovigilance committee decision	3 years	11/01/2024	11/04/2024		
Calcium Carbonate + Glycine + Dimethicone	Calcium carbonate/magnesium carbonate/simeticone	10 years	01/01/2029	01/04/2029		
Heptaminol HCl	Heptaminol HCl from removed entries in EURD list	13 years	28/01/2025	28/04/2025		
Hemicellulose + Papsin + Pepsin + Diastase	Non-reference	3 years	05/05/2026	03/08/2026		
fish oil + Borage seed oil + Flaxseed oil	Omega-3-acid ethyl esters	1 year	22/01/2024	01/04/2024	22/01/2025	01/04/2025
Besifloxacin (Ophthalmic)	Ofloxacin (topical use)	3 years	16/04/2024	15/07/2024		
Sodium Chloride + Potassium Chloride + Sodium Lactate + Glucose Anhydrous solution for I.V infusion	glucose (apart from glucose-1- 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	09/02/2034	12/01/2034		PSUR Frequency and DLP updated
Clobetason + Tetryzoline	Betamethasone / Tetryzoline	5 years	30/09/2024	29/12/2024		
Thiamine + Pyridoxine + Nicotinamide + Cyanocobalamin + Orotic acid + D panthenol + Folic acid	Cyanocobalamin / Pyridoxine / Thiamine	13 years	01/01/2025	04/01/2025		
Ferrous fumarate	iron / oral preparations	13 years	01/01/2025	01/04/2025		
Lesimurad	Lesimurad from removed entries in EURD list	2 years	21/12/2025	21/03/2026		
Hydroxyprogesterone	medroxyprogesterone	5 years	19/08/2026	17/11/2026		
Strontium Ranelate octahydrate	Strontium Ranelate from removed entries in EURD list	5 years	21/09/2028	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		
Soya Lecithin + Ascorbic acid + Thiamine + Riboflavin + Pyridoxine HCl) + Cyanocobalamin + Nicotinamide + Zn sulphate + Selenium yeast + DL alpha tocopherol acetate	ascorbic acid/folic acid/alpha-tocopherol/biotin/cholecalciferol/ cyanocobalamin/nicotinamide/pantothenic acid/pyridoxine hydrochloride/ retinol/riboflavin/thiamine	8 years	22/01/2029	22/04/2029		
Ascorbic acid + Thiamine + Riboflavin+ Pyridoxine + Cyanocobalamin + Nicotinamide	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		
Zn sulphate + Selenium + DL alpha tocopheryl acetate + Soya Lecithin + Silymarin						
Iron(III) hydroxide polymaltose complex	iron / oral preparations	13 years	01/01/2025	01/04/2025		

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Colour Indicators							
Blue	Recently added active ingredients & active ingredient combinations						
Yellow	PSUR Frequency and DLP updated						
Orange	PSUR Frequency updated						
Green	Superseded						
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			
Ibuprofen + Chlorzoxazone	ibuprofen, ibuprofen lysine (not indicated in ductus arteriosus), ibuprofen / caffeine	3 years	18/02/2026	19/05/2026			
Bacitracin zinc + Neomycin sulphate + Polymyxin B sulphate + Pramoxine hydrochloride	bacitracin, bacitracin / neomycin, bacitracin / polymyxin, bacitracin / neomycin / polymyxin, bacitracin / hydrocortisone / neomycin, bacitracin zinc / cysteine / glycine / neomycin / thiomine	9 years	03/05/2029	01/08/2029			
Nehivitol + Vakartan	Vakartan, hydrochlorothiazide / vakartan	3 years	30/04/2025	29/07/2025			
l-ornithine-L-aspartate	Ornithine from removed entries in EURD list	13 years	01/01/2025	01/04/2025			
Crisaborole	Crisaborole from removed entries in EURD list	1 year	13/06/2024	22/08/2024			22/08/2025
Mosapride	Japan only	1 year	30/01/2024	01/04/2024			01/04/2025
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			
Benproperine Phosphate	Non reference	1 year	13/12/2024	21/02/2025			13/03/2025
Erdafitinib	Chezoquinone from removed entries in EURD list	13 years	01/01/2025	01/04/2025			
Levonulnacriam	Milnacipran	3 years	30/04/2024	29/07/2024			
Luliconazole	ketocozazole	7 years	02/12/2023	01/03/2024			
Tetramethin + Pinromax batavide	Pimaricin	3 years	31/08/2026	29/11/2026			
Ascorbic acid + DL-alfa tocopherol acetate + N1k bisite + Sodium Selenite Pentahydrate + Vitamin A palmitate + Zinc gluconate	alfatocopherol / ascorbic acid / biotin / calcium pantothenate / cokecalciferol / cyanocobalamin / magnesium / manganese / pyridoxine / riboflavin / thiamine / vitamin a / zinc	23 years	01/01/2025	01/04/2025			next DLP updated on (06/06/2024)
Fluphenazine + Nortryptiline	Nortryptiline	5 years	31/03/2028	29/06/2028			
chlorphenamine + paracetamol + pseudoephedrine + Caffeine	chlorphenamine / paracetamol / pseudoephedrine	10 years	03/05/2035	01/08/2035			PSUR Frequency and DLP updated
Star Flower Oil + DL- tocopherol acetate	a-tocopheril, a-tocopherol, vitamin E	13 years	01/01/2025	01/04/2025			
Evening Primrose Oil + DL- tocopherol acetate	a-tocopheril, a-tocopherol, vitamin E	13 years	01/01/2025	01/04/2025			
Alginate acid + Calcium carbonate	alginate acid / aluminium oxide hydrated / sodium hydrogen carbonate, alginate acid / aluminium hydroxide / calcium carbonate / sodium carbonate	7 years	03/06/2024	01/09/2024			
Alginate acid + Calcium carbonate + Sodium bicarbonate	alginate acid / aluminium oxide hydrated / sodium hydrogen carbonate, alginate acid / aluminium hydroxide / calcium carbonate / sodium carbonate	7 years	03/06/2024	01/09/2024			
Sodium chloride + Potassium Chloride + Disodium hydrogen citrate + Glucose (oral administration)	Glucose (part from glucose-1-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			PSUR Frequency and DLP updated
Alsikiren + Amlodipine	alsikiren, alsikiren / hydrochlorothiazide	3 years	30/09/2024	29/12/2024			
Ursodeoxycholic acid + Chenodeoxycholic acid	Non reference	1 year	09/10/2024	18/12/2024			18/12/2025
Castor oil	Sodium nicosulfate	13 years	01/10/2025	30/12/2025			
Sublirda + Mebeverine	Amisulpride	3 years	20/01/2026	20/04/2026			
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			
Amoxicillin + Dioxacillin	Non reference	1 year	25/05/2024	03/08/2025			03/08/2025
Salbutamol + Guaifenesin	salbutamol	3 years	31/01/2026	01/05/2026			
Cefbuten	Cefbuten from removed entries in EURD list	5 years	02/07/2027	30/09/2027			
METHIONINE + L-LYSINE + ISOLEUCINE + PHENYLALANINE + L-HISTIDINE + L-leucine + L-threonine + L-tryptophan + Tyrosine	valine / histidine / isoleucine / leucine / lysine / methionine / phenylalanine / threonine / tyrosine / tryptophan	10 years	01/08/2028	30/10/2028			
Miconazole + Mometasone	Mometasone	5 years	22/05/2028	20/08/2028			
Simsvastatin + Sitagliptin	sitagliptin, metformin hydrochloride / sitagliptin	3 years	03/08/2026	01/11/2026			next DLP updated on (06/06/2024)
erythromycin + Sulfafurazole	erythromycin (Systemic use)	3 years	11/03/2025	09/06/2025			
Azithromycin + Dexamethasone	Non reference	6 months	30/04/2024	09/07/2024			
Erdafitinib	Newly authorized & FDA only	6 months	11/04/2024	29/06/2024			
sulfonacin + Mirabegron	Non reference	1 year	30/06/2024	08/09/2024			08/09/2025
finafloxacin	Ofloxacin (Topical use)	3 years	16/04/2024	15/07/2024			
ambroxol + doxycycline	ambroxol + doxycycline from removed entries in the EURD list	3 years	30/09/2025	29/12/2025			
Bronhexine + Salbutamol	salbutamol	3 years	31/01/2026	01/05/2026			
Salbutamol + Guaifenesin	Salbutamol from removed entries in the EURD list	3 years	31/01/2024	01/05/2024			
aescin + Diethylsalcilate	diethylamine-salcilate / escin	13 years	01/01/2025	01/04/2025			
Ezogabine	Retigabine from removed entries in EURD list	1 year	28/09/2024	07/12/2024			07/12/2024
N-acetylcysteine	N-acetylcysteine	5 years	12/09/2023	12/12/2023			12/12/2028
Betamethasone valerate + Neomycin Sulphate	betamethasone sodium phosphate / neomycin sulfate	9 years	01/01/2030	01/04/2030			
Tobramycin + lotenredinol etabonate	tobramycin (ophthalmic and otic use)	5 years	31/03/2026	29/06/2026			
Fluocanazole	Fluocanazole	3 years	31/01/2026	29/06/2026			next DLP updated on (06/06/2024)
Sodium Chloride + Sodium Bicarbonate + Borax + L- menthol	Sodium Chloride	13 years	24/11/2025	22/02/2026			
Calcium acetate + magnesium carbonate	Calcium Carbonate / magnesium carbonate from removed entries in the EURD list	13 years	01/01/2025	01/04/2025			
Aluminium hydroxide + Magnesium hydroxide	Aluminium hydroxide gel / Dimeticone / Magnesium hydroxide	13 years	01/01/2025	01/04/2025			

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Colour Indicators								
Blue	Recently added active ingredients & active ingredient combinations							
Yellow	PSUR Frequency and DLP updated							
Orange	PSUR Frequency updated							
Green	NEW LISTINGS							
Guaifenesin + Paracetamol + Oxometazoline + Sodium benzoate	oxometazoline	13 years	11/03/2025	09/06/2025				
Azintamide + Pancreatin + Hemicellulase	simeticone, pancreatin / simeticone, dimethicone / pancreatin, pancreatic enzymes, pancreatic extracts, pancreatin	9 years	02/04/2028	01/07/2028				
Paracetamol + Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride Chlorpheniramine Maleate	dextromethorphan / paracetamol / phenylephrine	6 years	03/11/2023	01/02/2024				
Bepotastine	epinastine	5 years	31/10/2027	29/01/2028				
Caffeine + Ergotamine + Paracetamol + Metoclopramide	Paracetamol (Non IV formulations)	13 years	21/12/2025	21/03/2026				
Allantoin + Onion extract + Heparin	Heparin	13 years	31/03/2025	29/06/2025				
Silymarin + Acetylcysteine	Acetylcysteine	5 years	13/09/2023	12/12/2023			12/12/2028	
Chlorpheniramine maleate + Ibuprofen + Pseudoephedrine	Ibuprofen / Pseudoephedrine	3 year	18/07/2026	16/10/2026				
Paracetamol + Panabron + Pyrilamine	Paracetamol (Non IV formulations)	13 years	21/12/2025	21/03/2026				
tretinoin + Fluocinolone + Hydroquinone + Euselex oil (Topical)	Tretinoin (topical formulations)	5 years	31/08/2027	29/11/2027				
Benfotiamine + Pyridoxine + Cyanocobalamin	cyanocobalamin / pyridoxine / thiamine	13 years	01/01/2025	01/04/2025				
thioctic acid + benfotiamine + Cyanocobalamin	thioctic acid	13 years	01/01/2025	01/04/2025				
Salicic acid + L-Iron	lactic acid / iron, urea	13 years	30/04/2025	29/07/2025				
Guaifenesin + Dextromethorphan + Pseudoephedrine + Chlorpheniramine	chlorpheniramine / dextromethorphan / pseudoephedrine	13 years	01/12/2025	16/03/2026				
Halfbar extract + methenamine	methenamine	13 years	02/08/2025	31/10/2025				
Daivobet		2 years	31/08/2026	29/11/2026				
Suvorexant	Daivoresant	1 year	06/01/2024	16/03/2024	17/03/2025	06/01/2025		new DLP updated on (06/06/2024)
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				
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 / camphor / hydroxyethyl salicylate / benzyl nicotinate	5 years	20/04/2027	19/07/2027				
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 (From removed entries in the EURL list)	6 years	03/11/2023	01/02/2024				
Collagenase Clostridiopeptidase A	collagenase clostridium histolyticum (all indications except for treatment of Dupuytren's contracture and Peyroni's disease) (From removed entries in the EURL list)	3 years	31/12/2025	31/03/2026				
Chlorpheniramine + Acetylcysteine	Acetylcysteine	5 years	13/09/2023	12/12/2023			12/12/2028	
Cerebrolysin	PV committee decision	6 months	01/05/2024	10/07/2024				
Calcium 2-oxo-3-phenyl propionate + Calcium-3-methyl-2-oxo valerate + Calcium-4-methyl-2-oxo valerate + Calcium-dl-2-hydroxy-4-(methylthio) butyrate + Calcium -3-methyl-2-oxo butyrate + L-histidine + L-lysine + L-threonine + L-tryptophan + L-tyrosine	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				
Allantoin + Cepae Fluid Extract + Heparin sodium	heparin	13 years	31/03/2025	29/06/2025				
Di-iodohydroxy quinoline + Phthalyl Sulfathiazole + Streptomycin Sulfate + Homotrimethyl bromide	ephedrine hydrochloride / sulfathiazole	7 years	03/11/2025	01/02/2026				PSUR Frequency and DLP updated
Tretinoin + Fluocinolone Acetonide + Hydroquinone	Tretinoin (topical formulations)	5 years	31/08/2027	29/11/2027				
Simeticone + Dill Oil	Non reference	1 year	11/09/2024	20/11/2024			28/09/2025	
Ginseng Powder + Wheat Germ Oil + Bee Pollen Extract Powder + Safflower Oil + "Lecithin from Soyabean phosphatides 60% Lecithin" + L-Arginine as Monohydrochloride + D-Biotin + Copper Sulphate anhydrous + Calcium phosphate dibasic anhydrous + Folic Acid + Dried Ferrous Sulphate + Potassium Iodide + L-Lysine as Monohydrochloride + Light Magnesium Oxide + Manganese Sulphate Monohydrate + Niacinamide (Nicotinamide) + Potassium Sulphate + Calcium D Pantothenate + Riboflavin (Vit. B2) Lyophilized Royal Jelly + Selenium Yeast 0.2% + Disodium Monooxotrisoate (R13 + Vitamin A palmitate + Vitamin D3 + D1 Alpha tocopherol + Vitamin B1 + Nicotinamide, Ascorbic acid (as calcium ascorbate) + Calcium D Pantothenate + Para amino benzoic acid + Vitamin B2 + Vitamin B6 + Vitamin B12 + Biotin + Folic Acid + L-lysine Hcl + Calcium (as phosphate dibasic) + Iron (as ferrous sulphate dried) + Copper (as sulphate pentahydrate) + Potassium (as sulphate) + Manganese (as sulphate) + Zinc (as sulphate) + Rutin + Pollen extract	iron in combination with folic acid and other substances	13 years	01/01/2025	01/04/2025				
Ginseng Powder + Wheat Germ Oil + Bee Pollen Extract Powder + Safflower Oil + Lecithin + L-Arginine as Monohydrochloride + Boron Gluconate + D-Biotin + Chromium yeast (GTF yeast) Copper Sulphate anhydrous + "Total Calcium (calcium Carbonate, Calcium phosphate dibasic)" + Folic Acid + Dried Ferrous Sulphate + Potassium Iodide + L-Lysine Mono-hydrochloride + Magnesium Oxide Heavy + Manganese Sulphate Monohydrate + Molybdenum yeast + Nickel sulphate hexahydrate + Niacinamide (Nicotinamide) + Potassium Salicylate + Calcium Phosphates + Ferrous fumarate + Vitamin B12 + Folic acid + Ascorbic acid + Manganese Sulphate equivalent to manganese + Copper sulfate equivalent to copper	iron in combination with folic acid and other substances	13 years	01/01/2025	01/04/2025				

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Colour Indicates							
Blue	Recently added active ingredients & active ingredient combinations						
Yellow	PSUR Frequency and DLP updated						
Orange	PSUR Frequency updated						
Green	Superseded						
Vitamin A + Ascorbic acid (Vitamin C) + Cholecalciferol (Vitamin D) + Tocopherol (Vitamin E) + Thiamine Mononitrate (Vitamin B1) + Riboflavin (Vitamin B2) + Nicotinamide (Nicotinamide) + Pyridoxine Hydrochloride (Vitamin B6) + Cyanocobalamin (Vitamin B12) + Calcium Pantothenate + Folic Acid + Iron (elemental) + Magnesium + Copper	iron in combination with folic acid and other substances	13 years	01/01/2025	01/04/2025			
Ciprofloxacin + Tinidazole	Ciprofloxacin (systemic use)	5 years	02/04/2028	01/07/2028			
Ciprofloxacin + Metronidazole	Ciprofloxacin (systemic use)	5 years	02/04/2028	01/07/2028			
Dibexamide	Dibexamide + Metronidazole from the EDA list	1 year	25/10/2024	03/01/2025			03/01/2025
Thiamine HCL + pyridoxine HCL + cyanocobalamin + Folic acid	cyanocobalamin / pyridoxine / thiamine	13 years	01/01/2025	01/04/2025			
Dried aluminium hydroxide gel + Magnesium hydroxide	aluminium hydroxide gel / Dimeticone / Magnesium hydroxide	13 years	01/01/2025	01/04/2025			
Acetylcysteine + Hydroxypropyl methylcellulose	Acetylcysteine	5 years	13/09/2023	12/12/2023			12/12/2028
Dry extract of belladonna/ phenobarbital	phenobarbital	8 years	27/01/2028	26/04/2028			
Dihydroxyquinolone + Streptomycin + Hvosaine N-Butyl bromide	Non reference	5 years	12/11/2023	10/02/2024			10/02/2029
Carbinoxamine maleate	loratadine	5 years	02/02/2027	03/05/2027			
Brompheniramine Maleate + Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride	Chlorphenamine / dextromethorphan hydrochloride / phenylephrine hydrochloride from removed entries in the EURD list	13 years	01/01/2025	01/04/2025			
Sodium Chloride + Potassium Chloride + Calcium Chloride + Dextrose + Water for Injection	glucose (apart from glucose-1-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 and/or sodium acetate (intravenous or parenteral use)	10 years	02/09/2034	01/12/2034			PSUR Frequency and DLP updated
Hydroquinone + Tretinoin + Dexamethasone	tretinoin (topical formulations)	5 years	31/08/2027	29/11/2027			
Simeticone + Mosapride	according to Mosapride submission in the EDA list	1 year	30/01/2024	01/04/2024			01/04/2025
Freeze dried chymotrypsin	Alpha chymotrypsin from Removed entries in the EURD	13 years	03/07/2025	01/10/2025			
Paracetamol + Drotaverine + Caffeine	caffeine / drotaverine hydrochloride / metamizole sodium	3 years	07/01/2024	06/04/2024			
Caffeine + Ergotamine + Algin	caffeine / ergotamine	3 years	30/11/2025	28/02/2026			
Betamethasone valerate + Gentamicin sulphate + Clotrimazole	betamethasone dipropionate / clotrimazole / gentamicin	13 years	01/01/2025	01/04/2025			

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Colour	Indicates							
Blue	Recently added active ingredients & active ingredient combinations							
Yellow	PSUR Frequency and DLP updated							
Orange	PSUR Frequency updated							
Green	Not applicable							
Hyoescamine	Pharmacovigilance committee decision	2 years	31/08/2025	29/11/2025				
Carteolol + Latanoprost	latanoprost / timolol	5 years	04/06/2027	02/09/2027				
Piroxicam + Nicotinamide	Piroxicam	3 years	01/04/2026	30/06/2026				
Imidafenacin	Mirabegron	3 years	30/06/2024	28/09/2024				
Ebastine/ Pseudoephedrine	ebastine / pseudoephedrine from removed entries of the EURD list	5 years	31/05/2028	29/08/2028				
Naphazoline hydrochloride + Chlorpheniramine maleate	naphazoline, naphazoline / zinc sulphate	12 years	31/07/2024	29/10/2024				
Naphazoline hydrochloride + Chlorpheniramine maleate + Zinc sulphate	naphazoline, naphazoline / zinc sulphate	12 years	31/07/2024	29/10/2024				
Naphazoline hydrochloride + Chlorpheniramine maleate + Methylene blue	methylthionium chloride	3 years	05/05/2026	03/08/2026				
silver sulfadiazine + Panthenol	Silver sulfadiazine	5 years	15/09/2025	14/12/2025				
Iodochlorhydroxyquin + Hydrocortisone	clioquinol / betamethasone valerate	9 years	01/01/2030	01/04/2030				
Acetate								
Chlorpheniramine maleate + Ibuprofen + Pseudoephedrine + caffeine	Ibuprofen / Pseudoephedrine	3 years	18/07/2026	16/10/2026				
Picramatide	FDA only							
Paracetamol + Dantrolene sodium	Dantrolene	13 years	07/08/2024	05/11/2024				
Eldcalcitol	calcitriol	5 years	31/01/2025	01/05/2025				
Nateglinide	nateglinide from removed entries in the EURD list	3 years	30/06/2026	28/09/2026				
Polycarbophil	polycarbophil from removed entries in the EURD list	13 years	13/02/2025	14/05/2025				
Calcichine + Frobenicid	Calcichine	5 years	30/07/2028	28/10/2028				
Pepsin + Papain + Saazyme	amylase / bromelain / chymotrypsin / lipase / pancreatin / papain / rutoside / trypsin, trypsin/ bromelain/ rutoside trihydrate	13 years	01/01/2025	01/04/2025				
Idroclamide	idroclamide from removed entries in the EURD list	13 years	18/06/2025	16/09/2025				
Paracetamol + Pseudoephedrine + Carboxamine	paracetamol / pseudoephedrine	5 years	28/06/2028	26/09/2028				
Carboxamine maleate + Phenylephrine hydrochloride	Carboxamine maleate/ Phenylephrine hydrochloride from removed entries in the EURD list	13 years	01/01/2025	01/04/2025				
Simethicone + Calcium Carbonate	Simethicone/ Calcium Carbonate from removed entries in the EURD list	13 years	01/01/2025	01/04/2025				
Enoxacin	Ciprofloxacin (systemic use)	5 years	02/04/2028	01/07/2028				
Dextromethorphan Hydrobromide + Bromethazine Hcl	Dextromethorphan	5 years	01/11/2026	30/01/2027				
Nebivolol + Amlodipine	Non reference	1 year	31/03/2024	09/06/2024				09/06/2025
Oxetetracycline + Nystatin + Clobetasone	Non reference	1 year	25/10/2024	03/01/2025				03/01/2026
Roxadustat	Roxadustat	6 months	16/12/2023	24/02/2024	16/06/2024			25/08/2024
Ascorbic Acid + Copper + Folic acid + Nicotinamide + Pantothonic Acid + Pyridoxine + Riboflavin (Vitamin B2) + Thiamine (Vitamin B1) + Vitamin B12 + Cyanocobalamin + Vitamin E + Zinc	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				
Thiamine HCL/ Riboflavin Phosphate/ pyridoxine HCL/ cyanocobalamin/ Folic acid	cyanocobalamin / pyridoxine / thiamine	13 years	01/01/2025	01/04/2025				
Glimepiride + Metformin	Metformin	3 years	01/04/2024	30/06/2024				
ALANINE + ARGININE + ASPARTIC ACID + CYSTEINE + Glutamic acid + HISTIDINE + ISOLEUCINE + Leucine + LYSINE + METHIONINE + PHENYLALANINE + Proline + Serine + THREONINE + TRYPTOPHAN + Tyrosine + Valine	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				
Ascorbic Acid (Vitamin C) + Biotin + Ferrus Fumarate + Folic Acid + Ginseng + Magnesium Sulphate + Neotilinamide + Pyridoxine Hydrochloride (Vitamin B6) + Riboflavin (Vitamin B2) + Royal Jelly + Selenium + Vitamin A (Retinol Palmitate) + Vitamin B1 (Thiamine) + Vitamin B12 + Cyanocobalamin + Vitamin E + Zinc Sulfate Monohydrate	iron in combination with folic acid and other substances	13 years	01/01/2025	01/04/2025				
Glycine + L-Arginine + L-Histidine + L-Isoleucine + L-Leucine + L-Lysine + L-Methionine + L-Phenylalanine + L-Threonine + L-Tryptophan + L-Valine + Sorbitol	amino acid combinations/ glucose/ with or without electrolytes / mineral compounds (i.v. application)	5 years	03/06/2026	01/09/2026				
Paracetamol + Grindelia soft extract + Gekesium soft extract	paracetamol (non IV formulations)	13 years	21/12/2025	21/03/2026				
mystatin + zinc oxide	mystatin	13 years	12/08/2025	10/11/2025				
amloride + hydrochlorothiazide + Atenolol	amloride / hydrochlorothiazide / timolol	8 years	03/06/2025	01/09/2025				
erythromycin + Isotretinoin	erythromycin / isotretinoin, isotretinoin (topical formulations) from removed entries in the EURD list	3 years	31/08/2024	29/11/2024				
Potassium Sodium Hydroxen Citrate	citric acid / potassium / sodium	13 years	01/01/2025	01/04/2025				
Magnesium carbonate + Sodium bicarbonate + Citric acid	citric acid / magnesium / sodium, citric acid anhydrous / light magnesium oxide / sodium picosulfate	13 years	01/01/2025	01/04/2025				
Vonoprazan + Amoxicillin + Clarithromycin	Non reference	1 year	01/01/2025	12/03/2025				
Rimantadine	Rimantadine from removed entries in the EURD list	5 years	31/10/2024	29/01/2025				
Mebeverine + Dimethicone	Non reference	5 years	31/03/2024	29/06/2024				
ascorbic acid + paracetamol + phenylephrine hydrochloride + Caffeine anhydrous	ascorbic acid / paracetamol / phenylephrine hydrochloride	5 years	15/06/2025	13/09/2025				
Bupropion hydrochloride + Dextromethorphan hydrochloride	FDA only	1 year	01/01/2025	12/03/2025				
Paracetamol + Hyoscine hydrobromide + Codeine phosphate + Caffeine monohydrate	Non reference	1 year	01/01/2025	12/03/2025				
Paracetamol + Pholcodine + Pseudoephedrine	Non reference	1 year	07/02/2024	17/04/2024				
Munirocin/ Fluticasone mronionate	Non reference	1 year	31/03/2025	06/09/2025				
Fluorometholone + Cromoglycate Sodium	cromoglicic acid	5 year	02/01/2025	05/02/2027				
Snake venom anti-serum	Non reference	3 years	14/09/2024	13/12/2024				
Polyvalent anti-viper venom serum	Non reference	3 years	14/09/2024	13/12/2024				
Anti-scorpion serum polyvalent	Non reference	3 years	14/09/2024	13/12/2024				
Typhoid and Tetanus Vaccine	Non reference	3 years	31/03/2024	31/03/2025				
Cholera Vaccine	Non reference	3 years	26/10/2026	26/10/2026				
Apis Mellifera purified bee venom	Non reference	5 years	07/02/2027	30/09/2027				
Recombinant Hirusin "Systemic"	Non reference	3 years	31/01/2024	30/04/2024				
COVID-19 Virus Cell inactivated	Non reference	1 year	28/12/2023	03/07/2024	28/12/2024			07/03/2025
Measles, Mumps & Rubella Vaccine live, Attenuated Freeze Dried	Non reference	3 years	31/03/2024	30/06/2024				
Hepatitis B Vaccine	Non reference	2 years	31/03/2024	29/06/2024				

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Colour Indicators	Recently added active ingredients & active ingredient combinations								
Blue	PSUR Frequency and DLP updated								
Yellow	PSUR Frequency updated								
Orange	PSUR Frequency updated								
Green	DLP UPDATED								
Magnesium sulphate + Anhydrous disodium hydrogen phosphate	magnesium sulfate / sodium sulfate / potassium sulfate	3 years	05/08/2024		03/11/2024				
Betamethasone+ Gentamicin+ Chloroquinol+ Tolofate	gentamicin (topical use)	8 years	03/03/2025		01/06/2025				
Chlorphenesin + benzoic acid + zinc oxide	Chlorphenesin from removed entries in the EURD list	13 years	01/01/2025		01/04/2025				
Magnesium sulphate + Polyethylene glycol + Potassium chloride + Sodium chloride + Sodium sulphate	FDA only	6 months			09/02/2025				
Sodium chloride + Potassium chloride + aloe Vera gel	sodium chloride (nasal drops)	13 years	01/01/2025		01/04/2025				
iron hydroxide polymaltose + Vitamin B12 + Copper Sulphate anhydrous + Vitamin C + Folic acid + Zinc sulphate monohydrate	iron in combination with folic acid and other substances	13 years			01/04/2025				
Substitiamine + Zinc sulphate	substitiamine	13 years	28/07/2025		29/05/2025				
Recombinant hirudin "Topical"	Non reference	5 years	01/12/2024		01/03/2025				
Risedronate sodium + Calcium carbonate	risedronate, risedronate, risedronate/calcium/colecalciferol	5 years	31/03/2026		29/06/2026				
Beta Carotene + Calcium pantothenate + Vitamin B6 + Vitamin C + D-alpha-tocopherol acid succinate + Zinc Sulphate monohydrate	non reference		01/01/2025		04/01/2025				
Betamethasone valerate + gentamicin + tolofate + indochlorhydroquin	betamethasone / gentamicin	13 years	01/01/2025		04/01/2025				
diethylamine salicylate + Amysalicylate	diethylamine salicylate	13 years	01/01/2025		01/04/2025				
Pancreatin + Papain + Ox-bile extract (contains not less than 45% of cholic acid)	amylase / bromelain / chymotrypsin / lipase / pancreatin / papain / rutoside / trypsin, trypsin/ bromelain/ rutoside trihydrate	13 years			01/04/2025				
Iroxubutanol	subbutanol	3 years	31/01/2026		01/05/2026				
Droxidopa	non reference	5 years	15/07/2025		13/10/2025				
Guaifenesin + Diphenhydramine Hcl + Phenylephrine Hcl	Guaifenesin/ Phenylephrine Hydrochloride from removed entries in the EURD list	13 years			01/01/2025				
Guaifenesin + Bromhexine	Bromhexine	3 years	30/09/2025		29/12/2025				
Trifluoperazine	Trifluoperazine from removed entries in the EURD list	13 years	01/10/2025		30/12/2025				
Vitamin A + Beta carotene + Thiamine (Vitamin B1) + Vitamin B2 (Riboflavin) + Niacinamide + Pyridoxine Hydrochloride (Vitamin B6) + Vitamin B12 (Cyanocobalamin) + Vitamin C (Ascorbic acid) + Vitamin D3 (Cholecalciferol) + Vitamin E + Biotin + Calcium Pantothenate + Folic acid + Minerals + Calcium Carbonate + Chromium Chloride + Copper + Potassium Iodide + Zinc + Iron + Magnesium + Manganese + Molybdenum + Selenium	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				
lidojoh + lidocaine	lidocaine (topical use)	8 years	30/09/2028		29/12/2028				
Caffeine + Camylofin + Ergotamine + Meclozamine + Propylphenazone	caffeine / ergotamine	3 years	30/11/2025		28/02/2026				
Ascorbic acid + Chlorpheniramine + Dextromethorphan + Paracetamol + Phenylephrine	Chlorpheniramine / dextromethorphan hydrobromide / paracetamol	6 years	03/11/2024		01/02/2025				
Wood charcoal + Rhei radix + Sulfur sublimed + Senna folium	non reference	10 years	01/01/2024		01/04/2024				
Borax + Sodium Bicarbonate + Potash alum	non reference	13 years	24/11/2025		22/02/2026				
Dapoxetine + Sildenafil	non reference	1 year	30/09/2025		09/12/2025				
Hyoscine N butyl bromide + letopropfen	hyoscine butylbromide / paracetamol	13 years	10/08/2025		08/11/2025				
Vitamin B1 Vitamin B2 + Vitamin B6 + Nicotinamide + Calcium Pantothenate + Vitamin B12	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				
oxotemazine + Na benzoate + glycerol	oxotemazine	13 years	11/03/2025		09/06/2025				
guaiacolate	diosmetite	13 years	12/11/2025		10/02/2026				
Light kaolin + Pectin	Amphetamine from removed entries in the EURD list	13 years	01/01/2025		04/01/2025				
Amphetamine	Tropisetron from removed entries in the EURD list	3 years	28/2/2027		28/05/2027				
Tropisetron	FDA only	6 months	04/10/2024		13/12/2024				
Hexaflurin	Telbivudine from removed entries in the EURD list	3 years	31/08/2025		29/11/2025				
Telbivudine	Menadiol	13 years	01/01/2025		04/01/2025				
Acetomenaphthone-	non reference	13 years	01/01/2025		04/01/2025				
Sodium Lactate injection	Phenybutazone	13 years	28/02/2025		29/05/2025				
Chymotrypsin + Phenybutazone	diphenhydramine hydrochloride / paracetamol / pseudoephedrine hydrochloride	13 years	01/01/2025		01/04/2025				
Paracetamol + diphenhydramine HCl+ phenylephrine									
Zafirlukast	Zafirlukast from removed entries in the EURD list	3 years	31/12/2024		31/03/2025				
Bicaluterol	Japan only- Sevelamer	3 years	30/10/2024		28/01/2025				
Niroxibalin	Japan only	6 months	31/01/2026		01/05/2026				
Ceflavinac	non reference	1 years	18/12/2024		26/02/2025				
Mebeverine+ Dimethicone+	Mebeverine	13 years	10/11/2025		08/02/2026				
Paracetamol + ascorbic acid + enalapresin	ascorbic acid / enalapresin / paracetamol / ribendoxrine hydrochloride	13 years	01/01/2025		01/04/2025				
Magaldrate + Dimethicone	magaldrate	13 years	01/01/2025		01/04/2025				
Empagliflozin + Linagliptin + Metformin	FDA only	6 months	02/05/2024		11/07/2024				
liffegrast	FDA only- ciclesporin (topical use)	1 year	19/03/2025		28/05/2024				
Sorbitol+ Simethicone	simethicone	9 years	02/04/2028		01/07/2028				