

Batch Recalls in Switzerland 2005

Recalls from January 1, 2005 until December 31, 2005. All recalls are published in the Swissmedic Journal.
Classification of recalls according to the PIC/S standard operating procedure " Procedure for handling rapid alerts and recalls arising from quality defects".

Date of Recall Initiated	No of Product Licence	Brand Name	Dosage Form	Strength	Active Substance	Lot No	Marketing Autorization Holder	Class of Recall	Details of Defect
19. Dez. 2005	49'078	Eprex	Solution for injection	3000 IU/0.3 ml, 1000 IU/0.5 ml	Epoetin alfa	03LS07T (3000 IU), 04BS03L (1000 IU)	Janssen-Cilag AG	III	Stability data failing to support expiration date
05. Dez. 2005	55'411	Fem7 Combi 50	Medicated plaster	50 micrograms	Estradiol hemihydrate, Levonorgestrel	74BE17, 73BC05	Vifor SA	II	Stability data failing to support expiration date
05. Dez. 2005	53'855	Fem7 25/50	Medicated plaster	0.75/1.5mg	Estradiol hemihydrate	74AD13, 74BG27	Vifor SA	II	Stability data failing to support expiration date
22. Nov. 2005	43'494	Daktarin Mundgel	Gel	20mg/g	Miconazole	5HB0Y00	Janssen-Cilag AG	II	Dosing device deviation
18. Nov. 2005	53'056	Fortam	Powder for injection	1g	Ceftazidime	5007	GlaxoSmithKline AG	II	Failure of drug to dissolve properly
15. Nov. 2005	27'742	Undex	Spray	3,4mg, 70,7mg, 7,4mg and 22,5mg/1mL	Tolnaftate, Macrogol-400-undecylenae, Triclorcarbane, Glyceroltriacetate	045701, 046202, 055601	Melisana AG	II	Stability data failing to support expiration date
14. Nov. 2005	56'755	Fluesco	Tablets	20mg	Fluoxetinhydrochloride	412807	G. Streuli & Co. AG	III	Packaging, faulty e.g. wrong or missing batch number or expiry date

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09. Nov. 2005	42'049	Sibelium	Capsules, hard	5mg	Flunarizine	see detailed publication	Janssen-Cilag AG	II	Stability data failing to support expiration date
24. Okt. 2005	49'078	Eprex	Solution for injection	3000 IU/0.3 ml	Epoetin alfa	03LS04T	Janssen-Cilag AG	III	Stability data failing to support expiration date
12. Okt. 2005	47'887	Plak-Out , collutorio	Mouth wash	0.1%	Chlorhexidine, Polidocanol	05G1078	KerrHawe SA	III	Closure, faulty
03. Okt. 2005	54'865	Fortevital Tonikum	Oral solution	--	Ginseng, Ginkgo, Vitamins and Minerals	31214	Tentan AG	III	Non-compliance with specification (content of Selenium too high)
27. Sep. 2005	56'414	Sauerstoff medicinal	Gas	-	Oxygen	50727001	PanGas	II	Contamination, physical
26. Sep. 2005	56'414	Sauerstoff, medicinal	Inhalation vapour	2 Liter	Sauerstoff Ph.Eur.0417	50727001	PanGas	II	Contamination, chemical
14. Sep. 2005	53'358	Similasan Menosim, Globuli, homöopathisches Arzneimittel	Granules	7 granules several times daily	Acidum sulfuricum D6, Lilium lancifolium D10, Sepia officinalis D6	9271	Similasan AG	II	Labeling, faulty e.g. wrong or missing text or figures
14. Sep. 2005	52'802	Metacam ad us.vet., Suspension	Oral suspension	1,5 mg/mL	Meloxicam	114 ZM45-1, 064ZM84-4, 034ZM40-2, 123ZM80A-1, 053ZM94-9, 043ZM49-6, 102ZM98A-2	Boehringer Ingelheim (Schweiz) GmbH	II	Specifications not met

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15. Aug. 2005	56'699	Supradyn	Film-coated tablets		Vitamines and minerals	2957801, 2957802, 2957803, 2959201, 2959202, 3016701, 3061101, 3061102, 3093301, 3093302, 2957803, 2957804, 2959202, 2959203, 2959204, 3016702, 3016703, 3016704, 3061102, 3061103, 3061104, 3093302, 3093303, 3093304	Bayer (Schweiz) AG	III	Stability data failing to support expiration date
10. Aug. 2005	52'586	Fosicomp	Tablets	20 mg/12.5 mg	Fosinopril Natrium / Hydrochlorothiazid	see detailed publication	Bristol-Myers Squibb GmbH	III	Stability data failing to support expiration date
06. Jul. 2005	56'780	Paronex	Coated tablets	40mg	Paroxetinum	503239	Ecosol AG, Cham	III	Labeling, faulty e.g. wrong or missing text or figures
01. Jul. 2005	26'208	Tricodein Solco	Film-coated tablets	57.5mg	Codeinphosphat Hemihydrat	069708, 169805, 269908, 370105, 470203	Valeant Pharmaceuticals Switzerland GmbH	II	Stability data failing to support expiration date

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30. Jun. 2005	34'282	Betadine Lösung standardisiert, 50ml Sprühkopfflasche	Liquid preparation for cutaneous application	10mg/ml	Povidone, iodinated	41705A	Mundipharma Medical Company, Hamilton/Bermuda, Basel, Branch	III	Packaging defect
17. Jun. 2005	57'196	Torasem-Mepha 5	Tablets	5 mg	Torasemide	05 506 56	Mepha Pharma AG	III	Labeling, faulty e.g. wrong or missing text or figures
13. Jun. 2005	41'904	Motilium	Suppository	60mg	Domperidone	00HB385, 01AB114, 01DB686, 01JB707, 02HB343, 02JB765, 03EB259, 03IB354, 4DB1E00, 5AB2F00	Janssen-Cilag AG	III	Stability data failing to support expiration date
07. Jun. 2005	31'095	Florinef	Tablets	0.1mg	Fludrocortisone acetate	A088, A093, A098, A101, A105, A107, A110, A113, B113, A116, B116, A121, B121, A124, B124, A126	Bristol-Myers Squibb GmbH	II	Stability data failing to support expiration date
07. Jun. 2005	99'999	PAH p-aminohippuric acid . sodium salt	Solution for injection	20 %	p-aminohippuric acid	AC0540	Merckbiosciences AG	II	Contamination, physical

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31. Mai. 2005	41'904	Motilium	Suppository	10mg, 30mg	Domperidone	10mg: 00HB571, 01AB281, 01EB545, 01KB260, 02EB615, 02KB228, 03EB642, 03LB040, 4KB4E00 30mg: 00HB631, 00HB857, 01AB386, 01BB105, 01FB967, 01JB308, 01KB309, 02DB153, 02FB272, 02JB055, 02KB716, 03CB742, 03FB646, 03IB691, 04AB370, 4DB3G00, 4KB6100, 5AB0F00	Jansen-Cilag AG	III	Stability data failing to support expiration date
04. Mai. 2005	42'888	Vepesid	Capsules, soft	50mg	Etoposide	4E78674	Bristol-Myers Squibb GmbH	II	Contamination, physical
25. Apr. 2005	99'999	Zi Cao Gen Mu Li Tang	Capsules, hard		traditionelle TCM- Arzneimittelkombination	M118AL1	China Medical GmbH	II	Pyrrolizidine alkaloide content above acceptable limits
25. Apr. 2005	99'999	Fang Feng 13	Capsules, hard		traditionelles TCM- Kombinationsarzneimittel	403CM3723	China Medical GmbH	II	Pyrrolizidine alkaloide content above acceptable limits

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22. Apr. 2005	36'797	Natrium Bicarbonicum Bichsel 8.4%, 10ml (10 Ampullen)	Solution for infusion	8.4%	Sodium hydrogen carbonate	14044	Grosse Apotheke Dr. G. Bichsel AG	II	Packaging defect
20. Apr. 2005	17'097	Melisana Klosterfrau Melissengeist	Liquid preparation for oral use		Div. pflanzliche Destillate	4A0363, 4A0483, 4A0514, 430930, 430933, 490466	Melisana AG	III	Contamination, chemical
15. Apr. 2005	52'785	Importal Lösung	Oral solution	667 mg / ml	Lactitol monohydrate	M105, M106, M107, M108, M109, M212, M213, M214, M218, M219, M220, M318, M319, M320, M367, M375, M376, M425, M426 und M440	Novartis Consumer Health Schweiz AG	II	Crystals occurring
30. Mrz. 2005	28'270	Baldriparan, Dragées	Coated tablet	220mg Extrakt (gesamt)	Valeriana off., Humulus lupulus, Melissa off. (dry extract)	0091/03, 0093/03, 0094/03	Whitehall-Robins AG	II	Stability data failing to support expiration date
24. Mrz. 2005	99'999	Tussilagnis farfarae flos	Granules		Tussilagnis farfarae flos	363748	Complemedis AG	II	Pyrrrolizidine alkaloide content above acceptable limits
24. Mrz. 2005	99'999	Eupatorium fortunei herba	Granules		Eupatorium fortunei herba	353560	Complemedis AG	II	Pyrrrolizidine alkaloide content above acceptable limits

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24. Mrz. 2005	99'999	Belamcanda&Mahuang	Granules		traditionelles TCM-Kombinationsarzneimittel	45573	Complemedis AG	II	Pyrrolizidine alkaloide content above acceptable limits
24. Mrz. 2005	99'999	Mahuang&Gingko C	Granules		traditionelles TCM-Kombinationsarzneimittel	144042	Complemedis AG	II	Pyrrolizidine alkaloide content above acceptable limits
17. Mrz. 2005	99'999	Zi Cao Gen	Granules	5-9 g	Lithospermum radix	SV26771, S267BQ1, S267CG1	China Medical GmbH	II	Pyrrolizidine alkaloide content above acceptable limits
17. Mrz. 2005	99'999	Qian Li Guang	Granules	9-15 g	Herba Senecionis	SPO12BK1, SPO1271	China Medical GmbH	II	Pyrrolizidine alkaloide content above acceptable limits
17. Mrz. 2005	99'999	Pei Lan	Granules	3-10 g	Herba Eupatorii Fortunei	SW14861, S148BK1	China Medical GmbH	II	Pyrrolizidine alkaloide content above acceptable limits
07. Mrz. 2005	99'999	Pei Lan	Granules		Eupatorii Herba	0210396	Milestone International AG	II	Pyrrolizidine alkaloide content above acceptable limits
07. Mrz. 2005	99'999	Zi Cao	Granules		Lithospermi Radix	0210515	Milestone International AG	II	Pyrrolizidine alkaloide content above acceptable limits
04. Mrz. 2005	99'999	Pei Lan	Granules		Eupatorii flos	353560, D363456A, EE240802A	Lian Chinaherb AG	II	Pyrrolizidine alkaloide content above acceptable limits
04. Mrz. 2005	99'999	Qian Li Guang	Granules		Senecionis herba	LR0402016	Lian Chinaherb AG	II	Pyrrolizidine alkaloide content above acceptable limits

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02. Mrz. 2005	99'999	Kuan Dong Hua	Granules		Farfae Flos	0210325	Milestone International AG	II	Pyrrolizidine alkaloide content above acceptable limits
18. Feb. 2005	10'957	Pectocalmine gouttes	Liquid preparation for oral use		guaifenesine, ephedrine hydrochlorid, codeine phosphate, opium extract	23223, 25387	Vifor SA	II	Labeling, faulty e.g. wrong or missing text or figures
27. Jan. 2005	45'691	Allsan Bevital mit Magnesium	Coated tablets	--	Vitamins and Minerals	001013, 001014	Biomed AG	III	Stability data failing to support expiration date
27. Jan. 2005	45'690	Allsan Multivitamine und Mineralstoffe	Coated tablets	--	Vitamins and Minerals	002013, 002014, 002024, 002034, 002044	Biomed AG	III	Stability data failing to support expiration date
20. Jan. 2005	47'580	Apomorphinium chloratum	Solutions for injection	10 mg/ml	Apomorphine Hydrochloride	633105, 671207	G. Streuli & Co. AG	II	Contamination, physical
03. Jan. 2005	55'802	Bisoprolol-Mepha	Coated tablets	5 mg	Bisoprolol Fumarate	03 80 181, 03 80 182	Mepha Pharma AG	II	Contamination, chemical