

Batch Recalls in Switzerland 2006

Recalls from January 1, 2006 until December 31, 2006. All recalls are published in the Swissmedic Journal and on the Swissmedic website.
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 Authorization Holder	Class of Recall	Details of Defect
23. Nov. 2006	33'273	Aethoxysklerol	Solution for injection	1%, 30 ml	Polidocanol	31559	Globopharm AG	III	Contamination, physical
13. Okt. 2006	57'197	Neotracin	Eye ointment	3,5 mg/g and 250 UI/g	Neomycin and Bacitracin	411519, 412582	OmniVision AG	II	Stability data failing to support expiration date
10. Okt. 2006	39'259	Estracyt	Capsules, hard	140 mg	Estramustinphosphate	A090D, 48WGG4, B827B	Pfizer AG	III	Packaging defect
29. Sep. 2006	57'556	Neulasta Injektionslösung in vorgefülltem Pen (SureClick)	Injection		Pegfilgrastim	N1185AL04	Amgen Switzerland AG	II	Subpotency
22. Sep. 2006	53'602	Iomeron	Solution for injection	400 mg/ml, 50 ml	Iomeprol	M4353	Bracco Suisse SA	III	Mix-up of some products (rogues) with more than one container involved
03. Aug. 2006	46'969	Ultravist	Solution for injection	769mg (corresponds to 370mg/ml Iodine)	Iopromide	all batches	Schering (Schweiz) AG	II	Contamination, physical

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30. Jun. 2006	49'289	Grünvet Salbe ad us. vet.	Gel	20 and 50 mg	Methylsalicylate and camphor	04J042, 04J052, 04J062, 04L213, 05B081, 05I071, 05I081, 05I091, 06B161	Provet AG	II	Non-compliance with specification (e.g. assay, stability, fill/weight)
06. Jun. 2006	56'952	Naloxon	Solution for injection	0.4 mg/ml	Naloxone hydrochloride	01N-05	Orpha Swiss GmbH	II	Mix-up of some products (rogues) with more than one container involved
31. Mai. 2006	99'999	Schüssler Salben Nr 1 D6, Nr 2 D6, Nr 4 D6, Nr 7 D6	Ointment		div. Schüssler Salze (D6)	0604070 (Nr. 1, D6 500g), 0604071 (Nr. 2, D6, 50 g), 0604073 (Nr.4, D6, 50g), 0604074 (Nr. 4, D6, 500 g), 0604078 (Nr. 7, D6, 500 g)	Phytomed AG	III	Non-compliance with specification (e.g. assay, stability, fill/weight)
29. Mai. 2006	55'659	Bexin	Lozenges	25 mg	Dextrometorphan	C031, C 061, C071	Spirig Pharma AG	III	Stability data failing to support expiration date
26. Apr. 2006	46'419	Gastrosil	Solution for injection	10mg/2ml	Metoclopramide	BN 33315, BN 41716, BN 51517	Pfizer AG	III	Labeling, faulty e.g. wrong or missing text or figures

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18. Apr. 2006	45'535	Bepanthen Nasensalbe	Ointment	50 mg / g	Dexpanthenol	G3334, G3340, G3349, G3375, G3413, G3437, G3449, G3475, G3490, G3499, G3524, G3533, G3545, G3552, G3576, G3600, G3612	Bayer (Schweiz) AG	III	Antimicrobial conservation insufficient
01. Apr. 2006	12'175	Aphenylbarbit	Tablets	15 mg	Phenobarbital	425210	G. Streuli & Co. AG	II	Mix-up of products in containers
24. Feb. 2006	26'892	Haldol	Oral drops	2mg/ml drops 1x15ml	Haloperidol	01BB553, 01EB481, 01EB192, 02AB371, 02CB116, 02FB727	Janssen-Cilag AG	II	Packaging defect
16. Feb. 2006	56'506	Phenobarbital 20%	Injection	1ml	Phenobarbital	4051/3, 4051/4	Amino AG	II	Contamination, physical
12. Feb. 2006	41'390	Isoket 0.1%	Concentrate for solution for infusion	100ml	Isosorbide dinitrate	all batches	Schwarz Pharma AG	II	Contamination, chemical
12. Feb. 2006	45'371	Perlinganit	Solution for infusion	50ml	Glycerol trinitrate	all batches	Schwarz Pharma AG	II	Contamination, chemical

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24. Jan. 2006	56'520	Foradil Certihaler	Powder for inhalation	10 micrograms	Formoterol fumarate	K082A, K001, L759	Novartis Pharma Schweiz AG	II	Device is blocking
21. Jan. 2006	54'705	Estalis sequi	Transdermal patch	50/140 (8 Systeme), 50/250 (8 Systeme), 50/250 (24Systeme)	Estradiol hemihydrate, Norethisteronacetate	16485, 16480, 16481	Novartis Pharma Schweiz AG	III	Stability data failing to support expiration date
21. Jan. 2006	54'704	Estalis	Transdermal patch	50/250 (8 Systeme), 50/250 (24Systeme)	Estradiol hemihydrate, Norethisteronacetate	15945112, 15945111	Novartis Pharma Schweiz AG	III	Stability data failing to support expiration date
19. Jan. 2006	53'857	Hycamtin	Solution for injection	1mg	Topotecan HCl	3015HSW1, 3024HSW1, 3034HSW1, 3034HSW2	GlaxoSmithKline AG	III	Contamination, chemical