

# Batch Recalls in Switzerland 2004

Recalls from January 1, 2004 until December 31, 2004. 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
15.12.04	45'138	Nasivin	Liquid nasal spray	0.05%	Oxymetazolin Hydrochlorid	4558103, 4479601, 4427301, 4398201, 4398103, 4351805	Iromedica AG, St.Gallen (SG)	II	Stability data failing to support expiration date
10.12.04	41'936	Platinol	Concentrates for infusion	25mg/50ml	Cisplatin	3M54389	Bristol-Myers Squibb GmbH	II	Contamination with product on the outside
29.11.04	50'821	Prednison Galepharm	Tablets	50 mg	Prednisone	0104	Galepharm, Arbeitsgemeinschaft Schweizer Apotheker	II	Labeling, faulty e.g. wrong or missing text or figures
12.11.04	54'845	Cytosar	Solution for injection	2000 mg/20 ml	Cytarabine	BA33B	Pfizer AG	II	Contamination, physical
27.10.04	12'175	Aphenlybarbit	Tablets	15 mg	Phenobarbital	456608	G. Streuli & Co. AG	II	Mix-up of products in containers
05.10.04	30'274	Lipiodol Ultra-fluide	Injection	2.4 g / 5 ml	Iodine	04LU001B	Guerbet AG	III	Incompatibility while mixing with other drugs
22.09.04	51'407	Daivonex	Ointment	50 ug / g	Calcipotriol	Y7821	LEO Pharmaceutical Products Sarath Ltd.	III	Stability Issue: It is expected that assay and a degradation product of one batch will fail the specifications at end of shelf-life

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
21.09.04	56'558	Phenobarbital	Injection	200mg/ml	Phenobarbital	610407, 801104, 620406, 789807, 626209	G. Streuli & Co. AG, Uznach (SG)	I	Physical contamination (particulates)
17.09.04	40'792	Midro Caps	Capsules	14 mg (hydroxyanthracenoglycosides)	Sennae folium, dry extract (Sennoside)	01127.1, 02017.1, 03027.1	Midro Vertrieb AG	II	Stability data failing to support expiration date
15.09.04	36'335	Turexan	Emulsion	8.3mg, 16.6 mg, 5mg / 1g	acidum undecylenicum, Zinci undecylenas, Triclosanum	216831, 217356, 318872, 319191, 319577, 320562, 320685, 320941, 321189, 322691, 424858, 425041, 425369	Turimed AG, 8304 Wallisellen	II	Occurrence of crystals in the product
01.09.04	53'904	Durogesic TTS	Transdermal patch	50, 75, 100 mcg	Fentanyl	100ug /h: 03KB833/04B B228; 75ug/h: 03LB757/04A B091; 50ug/h:04BB 238	Janssen-Cilag, Baar (ZG)	II	Stability data do not support expiry date (loss of ethanol which may effect the release rate of the drug substance)
17.08.04		Gensulin M20 (20/80)	Suspension for injection	100 I.U./ml	Insulinum Humanum + Insulinum Isophanum	603004	Bioton Spolka z o.o. 02-516 Warszawa, ul. Staroscinska 5	II	Non compliance with specification - to much insulin in solution

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
30.07.04	54'975	Seretide Diskus	Powder for inhalation	50, 500 mcg	Salmoteroli xinafoas / Fluticasoni propionas	B122654 (CH) B1221 40 (AU) B1226 65 (NO)	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	Potential for the strip to tear during use. The numerical dose counter in the diskus appears to have continued to function.
19.07.04	54'681	Agnolyt	Capsules	3,85 mg / capsule	Vitex agnus-castus, dry extract	B0231579 B0207295 B0311715 B0326715 B0326962 B0345962 B0247715 B0409962 B0420134	Max Zeller Söhne AG	II	Non-compliance with specification (content of active ingredient too low)
16.07.04	46'877	Linola Halbfett	Emulsion	5.3 mg/g, 2.1 mg/g	9,11-Linolicacid 9,12-Linolicacid	202010, 202020, 202021, 202030, 202031, 306010, 306020, 306030, 306031, 201010, 201011, 201012, 201020, 201021, 303010, 303011, 303012, 303020, 303030	Medika AG, Aesch (BL)	III	Stability data failing to support expiration date
02.07.04	56'209	Abilify	Tablets	15 mg	Aripiprazol	3L68444	Bristol Myers Squibb GmbH, CH-8341 Baar	II	Stability data failing to support expiration date (dissolution)
30.06.04	54'716	System Sequi	Transdermal patch		Estradiol Mono u. Estr. - Norethisteron Kombi	04BS01K, 04AS105K	Janssen Cilag AG, Baar	II	Inconsistencies of localisation of two phase TTS in the package

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
25.05.04	53'904	Durogesic TTS	Transdermal patch	50, 75, 100 mcg	Fentanyl	siehe Link	Jannssen-Cilag AG, Baar	II	Non-compliance with specification
26.04.04	54'080	Oculotect Gel	Eye gel	1000 IU/g	Retinol palmitate	410153-1, 410153-2, 410220, 410007, 410153, 410181	Novartis Pharma Schweiz AG, Bern (BE)	III	Stability data failing to support expiration date
03.04.04	417	Tollwut impfstoff Mérieux	Injection	> 2.5 IU	inaktivierte Tollwutviren	X0071-7, X0253-7, X0253-5	Aventis Pasteur MSD AG	II	Contamination with non-inactivated virus
02.04.04		Actrapid MC suis	Injection	100 IE/ml	Insulin suis	503	Inselspital	II	Possible mix-ups with test medium
26.03.04	34'096	Tyroqualin	Tablets	0.15mg / 1mg / 1mg	Dequalinii Chloridum, Tyrothricinum, Lidocaini Hydrochloridum	9002, 9003, 0002, 0003, 1001, 1002, 2001, 2002, 2003, 2004	Spirig Pharma AG, Egerkingen (SO)	II	Stability data failing to support expiration date
18.03.04	47'192	Dolo-Arthrosenex	Cream	125 mg/g, 100 U.I./g, 10 mg/g	Hydoxyethylis salicylas/ Heparinum Natricum/ Dextrocamphora	100140, 115040, 203561, 208540, 301930, 307410, 100141, 107580, 115041, 203560, 208541, 301931, 307411	Whitehall-Robins AG, 6301 Zug	III	Stability data failing to support expiration date

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
08.03.04	53'869	Movicol Pulver	Powder for oral solution	13 g	Macrogol, NaHC03, KCl, NaCl	32245, 31949, 31431, 31432, 31098, 31099, 30593, 30333, 29944, 29779, 29778, 29395, 29396, 31921, 31922, 31116, 31117, 30803, 30386, 30011, 30012, 29598, 29599	Norgine AG 6343 Rotkreuz	III	Missing or incorrect information (leaflet or inserts)
27.01.04	49'926	Pulmofor retard	Capsules	50 mg	Dextromethorphan hydrobromide	19928, 21304, 21346, 22684	Vifor SA, Fribourg (FR)	II	Wrong product (label and contents are different products)
22.01.04	52'475	Modifast Müesli	Powders, oral		multivitamin and minerals	S016, S017, T003, T001	Wander AG, Neuenegg (BE)	III	Non-compliance with specification (e.g. assay, stability, fill/weight)
22.01.04	51'856	Modifast Crème	Powders, oral		multivitamin and minerals	S005	Wander AG, Neuenegg (BE)	III	Non-compliance with specification (e.g. assay, stability, fill/weight)
20.01.04	16'061	Halibut Plus	Capsules	7500 IU Vit.A 750 IU Vit.D	Halibut-liver oil	311	Merz Pharma (Schweiz) AG, Allschwil	II	Faulty labelling on primary package (Label for Halibut Plus instead of Halibut Classic)