

Batch Recalls in Switzerland 2008

Recalls from January 1, 2008 until December 31, 2008. 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
20. Nov. 2008	50'990	Similasan Nasentropfen	Ear drops			10589	Similasan AG	III	Specifications not met
21. Okt. 2008	57'864	Actilife Kieselerde, Pulver	Oral powder		terra silicea depurata	3305700, 3044200, 3305700	Sponser Sportnahrung AG	II	Contamination, physical
17. Okt. 2008	57'417	Neupro	Medicated plaster	2, 4, 6, 8 mg	rotigotinum	all	UCB-Pharma AG	III	Specifications not met
06. Okt. 2008	47'249	Fragmin, Injektionslösung	Injection	15'000 I.E./0.6ml	dalteparinum natricum	74204A51	Pfizer AG	II	Potential microbial contamination of sterile injectable product
09. Sep. 2008	56'510	Ephedrin HCl Amino	Solution for injection	5% 1 ml	ephedrinum hydrochloridum	4021/9	Amino AG	I	Mix-up with Papaverin HCl Amino
27. Aug. 2008	30'774	Depo-Provera 150	Injection	150 mg	medroxyprogesteroni acetat	all	Pfizer AG	II	Presence of glass particles
13. Aug. 2008	56'914	Optiderm Lotion	Cutaneous emulsion	30 mg / 50 mg	polidocanola / ureum	822501	Almirall AG	III	Non-compliance with specification (e.g. assay, stability, fill/weight)
11. Aug. 2008		Less	Ointment			all		III	no market authorization

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. Aug. 2008	57'688	Accusol 35	Solution for haemodialysis		natricum/calcium/magnesium chloridum	all	Baxter AG	II	Precipitate during application in the transfer lines
25. Jul. 2008	49'493	Acetalgin	Suppository	125 mg	paracetamolum	0730299	Streuli Pharma AG	III	Mix-up of patient informations from another product (Mefenamid Sup.)
25. Jul. 2008	43'035	Eutha 77 ad us. vet.	Injection	400mg/ml ; 100ml vials	pentobarbitalum	6764101, 7590103, 6696101	Provet AG	II	Contamination, physical (particles)
18. Jun. 2008	24'137	Scheriproct Salbe	Ointment	cinchocain. HCl 0.5%, prednisolon.-21-hexanoas 0.19%	cinchocainum HCl, prednisolonum-21-Hexanoas	73078B (10b) , 74084A (30g)	Bayer (Schweiz) AG	II	Stability data failing to support expiration date
18. Jun. 2008	56'414	Sauerstoff medicinal, PanGas			oxygenium	see dedicated publication	PanGas	III	Labeling mix-ups
17. Jun. 2008	29'221	Fluoro-uracil Valeant	Solution for injection	5000mg/100 ml	fluorouracilum	S623,S624,S625	Valeant Pharmaceuticals Switzerland GmbH	II	Contamination, physical; crystalline precipitate of Fluorouracil in vials
12. Jun. 2008	42'340	Super Mastitar ad us. vet.	Intramammary preparation for veterinary use	1 Mio IU / 500 000 IU / 500mg	benzylpenicillinum procainum, benzylpenicillinum kalicum, neomycin sulfas	see detailed publication	Veterinaria AG Grubenstrasse 40	III	Stability data failing to support expiration date
18. Apr. 2008	57'144	Somavert	Powder for injection	10 mg	pegvisomantum	P10298	Pfizer AG	II	Contamination, physical

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
20. Mrz. 2008	56'332	Heparin Bichsel + 46'240 Heparin Bichsel	Solution for injection	50+100 IU/ml and 1000+5000 IU/ml	heparinum	see detailed publication	Grosse Apotheke Dr. G. Bichsel AG	II	Contamination, chemical
20. Mrz. 2008	46'613	Heparin B. Braun	Solution for injection	25 000 IU/ 5ml	heparinum	all	B. Braun Medical AG	II	Contamination, chemical
15. Feb. 2008	55'383	Floxal DU	Eye drops	3 mg/ml	ofloxacinum	289477	Bausch & Lomb Swiss AG	II	Potential microbial contamination of sterile ophthalmic product
09. Jan. 2008	38'932	Doxiproct	Ointment	40 and 20 mg / g	calcii dobesilas, lidocainum hydrochloridum	H017, MFD 05/2007, MFD 05/2012	OM Pharma	III	Non-compliance with specification; viscosity too high