

Batch Recalls in Switzerland 2010

Recalls from January 1, 2010 until December 31, 2010. 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
29. Dez. 2010	48'317	Ecovent	Preparation for inhalation		salbutamolum		Sandoz Pharmaceuticals AG	III	Closure, faulty
27. Dez. 2010	40'087	Myocholine-Glenwood	Tablet	25mg	Bethanecholchlorid	diverse	Vifor SA	III	Specifications not met
10. Dez. 2010	37'919	Tylenol	Suppository	200mg	Paracetamol	10FQ095	Janssen-Cilag AG	III	Non-compliance with specification (e.g. assay, stability, fill/weight)
16. Nov. 2010	51'079	Methotrexat "Ebewe" + Fluorouracil "Ebewe" (60'186)	Solution for infusion		methotrexatum + fluorouracilum		Sandoz Pharmaceuticals AG	I	Contamination, physical
26. Okt. 2010	55'419	PegIntron	Powder for injection		peginterferonum alfa-2b	EU/1/00/131/031 -050 ; EU/1/00/132/031 -050	Essex Chemie AG	II	Container defect
26. Okt. 2010	31'489	GlucaGen Novo, Injektionspräparat	Powder and solvent for solution for infusion	1mg/ml	glucagonum ADNr	YW60469	Novo Nordisk Pharma AG	II	Container defect
21. Sep. 2010	584	Octagam	Solution for infusion	5% (584) und 10% (60323)	immunoglobulinum humanum normale		Octapharma AG	I	Cluster of UAW
14. Sep. 2010	29'152	Ben-u-ron	Suppository	diverse	Paracetamolium	Lot 531A102	Nutrimed SA	I	Packaging, faulty e.g. wrong or missing batch number or expiry date

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12. Mai. 2010	60'138	Clopidogrel Sandoz 75, Filmtabletten	Film-coated tablet	75mg	Clopidogrelum	diverse	Sandoz Pharmaceuticals AG	II	Deviation from GMP
13. Apr. 2010	672	Beriglobin	Solution for injection		immunoglobulinum humanum normale, hepatitis A virus antigenum, immunoglobulinum A	24640311J, 24740321E, 24740321G	CSL Behring (Schweiz) AG	III	Specifications not met
13. Apr. 2010	52'474	Immunine STIM Plus, Injektionspräparat; Immunate S/D	Solution for injection		Factor IX coagulationis humanus (bzw. Factor VIII)	LOT:VNC3J051-AC; VNC1J002-AD; VNC1J010-AJ	Baxter AG	II	Specifications not met
12. Apr. 2010	57'071	Norditropin NordiFlex	Injection	15mg	Somatropinum ADNr	YC70016	Novo Nordisk Pharma AG	III	Packaging, faulty e.g. wrong or missing batch number or expiry date
18. Feb. 2010	46'296	Xylonest	Solution for injection	10mg	prilocaini hydrochloridum		AstraZeneca AG	II	Non-compliance with specification (e.g. assay, stability, fill/weight)