

Communication of batch recalls in Switzerland

 Status: *Recalls 2003*

Ref.No ¹⁾	Date of recall initiated dd.mm.yy	No of prod. licence	Brand Name	Active Substance (INN)	Dosage Form	Strength	Lot No	Marketing Authorisation Holder	Class. of Recall (I, II, III) ²⁾	Details of Defect	Information on Distribution
12/2003	29.09.2003	52259	Damira	vitamins and others	Powders for oral solutions	different	305461	Wander AG, Neuenegg (BE)	III	Non-compliance with specification (e.g. assay, stability, fill/weight)	CH
11/2003	03.12.2003	N/A	Calcium-dinatrium-EDTA	Nactriumcalcium-edetat	Injections	1,9 g / 10 ml	665205	Apotheke Wülflingen, Winterthur (ZH)	I	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland
11/2003	26.11.2003	39528	Diprophos Ampullen	Betamethason Dipropionat, Betamethason Natriumphosphat	Injections	5 mg / ml, 2 mg / ml	03E2634A	Essex Chemie AG, Luzern (LU)	III	Mislabelling, wrong figures	Switzerland only
11/2003	11.11.2003	45259	Vitamin C-1000	Acidum Ascorbicum	Tablets	1000mg	0271-3080	Gisand AG, 3013 Bern	III	Change of the color of the tablets (pink).	0
11/2003	04.11.2003	54975	Seretide Diskus	Salmoteroli xinafoas / Fluticasoni propionas	Powders for inhalation	50 / 200 mcg	50/250mcg: 2H524, 2G083, 2H056, 2L023, 2L024, 2M013, 2N100	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	notch in the internal foil strip may provoke tearing of the foil strip during usage without discharge of the dose	48 countries

11/2003	04.11.2003	53898	Ventolin Diskus	Salbutamolom	Powders for inhalation	200 mcg	200mcg: 2L049, 2M098, 2N123	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	notch in the internal foil strip may provoke tearing of the foil strip during usage without discharge of the dose	48 countries
11/2003	04.11.2003	53390	Axotide Diskus	Fluticasoni propionas	Powders for inhalation	100 / 250 / 500 mcg	100mcg: 3A174, 2L180, 3A139 250mcg: 2N145, 2K203, 2M024 500mcg: 3A219, 2G180, 2H193, 2K180, 2L173, 2M059, 619	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	notch in the internal foil strip may provoke tearing of the foil strip during usage without discharge of the dose	48 countries
11/2003	04.11.2003	53021	Serevent Diskus	Salmoteroli xinafoas	Powders for inhalation	50 mcg	50mcg: 2N114, 2G230, 2K044, 2L020, 2M020, 2L019, 550	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	notch in the internal foil strip may provoke tearing of the foil strip during usage without discharge of the dose	48 countries
11/2003	06.10.2003	42408	Linola Fett, Emulsion	9,11-Linolicacid 9,12-Linolicacid	Emulsion	5,3 mg / g 2,1 mg / g	205131 205091	Medika AG, Aesch (BL)	III	Stability data failing to support expiration date	0
10/2003	30.09.2003	38837	Trasyolol, Infusionslösung	Aprotinin	Infusions	277.8 U. E.P./ 50ml 1111.1 U. E.P./ 200ml	CBHKK1 CBZHT1	Bayer (Schweiz) AG, Zürich (ZH)	II	Non-compliance with specification observed during routine follow-up stability studies	Switzerland, Germany, Hungary, Finland, USA
09/2003	02.10.2003	52191	Vesdil mite	Ramiprilum	Capsules	1.25 mg	DM269A3	AstraZeneca AG, Zug (ZG)	I	Correct product but wrong strength, with serious medical consequences	Switzerland only

09/2003	22.08.2003	49552	Bimboderm, Crème	Calciumpantothenate	Creams	50 mg / g	75311	Apotheke Dr. Portmann AG, Interlaken (BE)	II	composition not authorised (antimicrobial agents)	Switzerland
08/2003	21.08.2003	25848	Formo-Cibazol ad. us. vet., Paste	Formo-sulfathiazolum	Pastes	500 mg / 1 g	303010	Novartis Tiergesundheit AG, Basel (BS)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland, Austria, Sweden
08/2003	31.07.2003	49078	Eprex	Epoetin	Injections	1000, 2000, 3000, 4000 und 10000 U	according List	Janssen-Cilag, Baar (ZG)	III	Contamination, e.g. microbial spoilage, dirt or detritus, particulate matter	Switzerland and other countries
08/2003	31.07.2003	42778	Parapic, flüssig	Levomenthole, Mepyaminmaleate, Cineole, Polidocanole, Isopropanole	Liquid preparations for cutaneous application	20 mg / g 10 mg / g 12,5 mg / g 20 mg / g q.s.	155040	Biomed AG, Dübendorf (ZH)	III	Faulty packaging, e.g. wrong or missing batch number or expiry date	Switzerland
07/2003	28.07.2003	36229	Dexalocal, Salbe	Dexamethasonum	Ointments	1 mg / g	950012	Medinova AG, Zürich (ZH)	III	Stability data failing to support expiration date	Switzerland and other countries
07/2003	23.07.2003	44176	Aknex, Gel	Benzoylperoxide	Gels	0.05	301	Gebro Pharma AG, Liestal (BL)	III	Occurrence of white particles in the product	Switzerland
07/2003	16.07.2003	42989	OSA-Zahngel	Calciumpantothenate	Gels	15 mg / g	All lots on market	Iromedica AG, St.Gallen (SG)	III	Stability data failing to support expiration date	Switzerland only
07/2003	07.07.2003	49606	Solmucol collyre	N-Acetylcystein	Eye-drops	50 mg / ml	011001, 020301	IBSA Institut Biochimique SA, Pambio-Noranco (TI)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland only
07/2003	07.07.2003	49599	Astroglide, Flüssiges Gleitmittel	Polyquaternium-5	Semi-solid vaginal preparations	7.5 mg / g	All lots on market	Lagap SA, Vezia (TI)	III	Marketed without a new or generic approval	Switzerland
07/2003	25.06.2003	20777	Bacitracin Grossmann, Lyophilisat	Bacitracin	Powders for cutaneous application	10000 IE / Amp.	101175	Dr. Grossmann Pharmaca AG, Birsfelden (BL)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	-
05/2003	23.05.2003	55662	Dolomed, Kapseln 40 Stück und 120 Stück	Petasitidis Extractum Spissum	Capsules	25 mg	041010A, 041010B	Bioforce AG, Roggwil (TG)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland

05/2003	19.05.2003	47671	Paraplatin Infusionslösung	Carboplatin	Infusions	10 mg / ml	2G60812	Bristol-Myers Squibb GmbH, Baar (ZG)	I	Cross-contamination with other products	Austria, Germany, Switzerland, The Netherlands, Scandinavia, Denmark, France, Morocco
04/2003	03.04.2003	55662	Dolomed, Kapseln 120	Petastidis Extractum Spissum	Capsules	25 mg	122010A	Bioforce AG, Roggwil (TG)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland
03/2003	21.03.2003	53747	Ultiva Lyophilisat	Remifentanil	Lyophilisat (Stechampulle)	5 mg	C075787	GlaxoSmithKline AG, Münchenbuchsee (BE)	I	Lack of assurance of sterility	Austria, Belgium, Netherlands, Norway, Spain, Italy, Sweden, Switzerland
03/2003	18.03.2003	55559	Zyvoxid, Granulat zur Herstellung einer Suspension	Linezolid	Oral suspensions	20 mg / ml	75HKU	Pharmacia AG, Dübendorf (ZH)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland and other countries
02/2003	27.02.2003	30433	Valium Roche 10mg	Diazepam	Injections	10 mg / ml	B1030, B1036, B1037, B1039, B1041, B1045, B1046, B1048, B1051	Roche Pharma (Schweiz) AG, Reinach (BL)	II	Non-compliance with specification (e.g. assay, stability, fill/weight)	Switzerland and other countries
01/2003	16.01.2003	572	Epaxal	Hepatitis A virus, inactivated	Injections	24 IU	016022.01 und 3000037	Berna Biotech AG, Bern (BE)	I	Microbial contamination of sterile injectable or ophthalmic product	Switzerland and other countries

- 1) Communication in the monthly publication Swissmedic Journal
- 2) According to communication in monthly bulletin of IKS/OICM January 1998