



DRS/MtH/IEA.74

20 November 1998

Information Exchange System

Alert No. 74

Psorigon[®] skin cream - found to contain tretinoin and cortisone derivatives

Germany. The Federal Institute for Drugs and Medical Devices has issued a PIC Rapid Alert concerning a cosmetic skin preparation, Psorigon[®]. The product has been recalled after different formulations were found to contain cortisone derivatives (Psorigon[®] Skin Regenerator Cream) and tretinoin (two creams, lotion, shampoo). Neither cortisone derivatives nor tretinoin have been approved for use in cosmetics and these substances are liable to prescription as medical products in Germany.

It is known that Psorigon[®] products are distributed in Germany and the UK and further exportation to other countries is possible. The Institute has strong indications that Psorigon[®] products have been exported to Japan and that Psorigon[®] or a similar product was produced by a licensed manufacturer in Australia. Psorigon[®] was recently renamed PS-98[®] in the UK and Denmark. Investigations are continuing in Germany and the UK and the relevant authorities in Australia and Japan are taking measures to ascertain whether Psorigon[®] products are available on their respective markets.

[See also Pharmaceuticals Newsletter Nos. 9&10, September&October 1998]

Batch numbers concerned are as follows:

Cortisone derivatives

Product:

Psorigon[®] Skin Regenerator Cream :

Batch nos.

87-201/06 EU

070912

Tretinoin

Products:

Psorigon[®] Skin Regeneratory Cream

Psorigon[®] +C Skin Repair Cream

Psorigon[®] Body Lotion

Psorigon[®] Shampoo

Batch nos.

83-201/03

85-202/03 E

85-201/04 C

87-201/06 EU

87-201/07 CC (maybe 87-207/07 CC)

87-203/01 EXP.: 07-2000

85-201/05.

Reference: PIC Rapid Alert, Federal Institute for Drugs and Medical Devices, Berlin, 6 November 1998.

