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27 October 1992

DRS Information Exchange Service

ALERT No. 30

BENZARONE (FRAGIVIX®, VASOC®): SUSPENSION OF MARKETING AUTHORIZATION

Germany. The Federal Health Office has suspended the marketing authorization for four pharmaceutical products containing benzarone, a compound with some serotonin antagonistic activity, indicated for the treatment of venous disorders. The products concerned are:

Fragivix® and Fragivix®-forte, and Fragivix® cream: Sanol
Vasoc®: Lindopharm

Parallel-imported products are marketed by several manufacturers.

The Office took this decision on the basis of several reports of toxic hepatitis, including a fatal case involving a patient with pre-existing liver damage, possibly due to hepatitis-B.

The approved product information was already modified several years ago to contain a warning against the use of benzarone by patients with liver impairment.

The Office stresses the importance, both for doctors and patients, of reading the product information in order to be aware of any changes in the text brought about by recent developments. Patients should always inform their doctor of any concurrent disease and medication.

References:

1) Press release 45/1992 from the Federal Health Office, Berlin, dated 20 October 1992.

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