

News Release



THE BOOTS COMPANY

MANOPLAX

Telephone: 0602 506111

Boots Pharmaceuticals treatment for congestive heart failure, Manoplax (Flosequinan), is being voluntarily withdrawn from sale immediately. The drug was launched with full regulatory approval in the UK in September 1992 and in the US in March 1993.

A major study among 3,000 patients - PROFILE - was initiated in July 1991 in North America and Scandinavia to establish the effects of Manoplax on survival. In April 1993 preliminary survival results showed increased mortality among patients given 100 mg daily and the Company withdrew that strength in the UK and advised UK and US physicians to use lower strength doses. An increase in hospitalisations of patients on the 75 mg dose of Manoplax has been seen in further interim analyses of data from this study. In view of these data, the continued use of Manoplax can no longer be recommended. Doctors are being advised to assess current Manoplax patients as soon as possible and to institute alternative treatments wherever necessary. The licensing authorities in the UK and the US have been fully informed of this development.

The implications of this decision are now being reviewed, with particular regard to any restructuring requirements. Costs associated with this will reduce the savings on marketing and research expenditure. The net effect when taken together with the loss of revenue is expected to have a small positive impact on cash flow and profits for this year. However, there will also be write-offs of stock and provisions against manufacturing facilities which are unlikely to exceed £35 million.

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In other therapeutic areas Boots Pharmaceuticals research has been successful, notably with ibuprofen for the treatment of many forms of inflammation and pain. The current research programme includes, in clinical development:

- an anti-obesity agent at an advanced stage
- a treatment for schizophrenia
- an anti-diabetic agent for patients with non-insulin dependent diabetes

and at pre-clinical stage:

- an anti-inflammatory for use in asthma
- a novel anti-depressant

- E N D S -

For further information, please contact:

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19th July 1993

July 16, 1993

DEAR "DOCTOR LETTER"
REVISED U.S. VERSION (3:34 pm - 7/16)

Dear Doctor

RE: Withdrawal of MANOPLAX® (flosequinan)

This letter is to inform you that after further analysis and review of additional efficacy data from the PROFILE survival study, Boots Pharmaceuticals, Inc. is voluntarily withdrawing from sale MANOPLAX®, (a drug used for the treatment of heart failure). We have seen on preliminary analysis that after three months of treatment hospitalization for symptoms of congestive heart failure were increased compared to placebo. This new information, coupled with the previously reported mortality data, has led to our decision to withdraw the drug.

It is important to follow your patients carefully after withdrawal from MANOPLAX® as preliminary data suggest that some patients withdrawn from MANOPLAX may demonstrate increased congestive heart failure symptoms.

Please contact us at 1-800-... if you have any questions or require further information.

Sincerely,

Dear Doctor

RE: WITHDRAWAL OF MANOPLAX (FLOSEQUINAN)

This letter is to inform you that Manoplax, a drug used for the treatment of heart failure, is being voluntarily withdrawn from sale in the UK by Boots Pharmaceuticals Ltd.

In April 1993 we informed you of the preliminary results of the PROFILE survival study which showed increased mortality at 100 mg of Manoplax. We therefore withdrew the 100 mg tablet and recommended a maximum dose of 50 mg once daily. An increase in hospitalisations of patients on the 75mg dose of Manoplax has been seen in further interim analyses of data from this study. In view of these data, the continued use of the 50mg dose can no longer be recommended.

We advise that patients being treated with Manoplax should be assessed as soon as possible and alternative treatment instituted as considered necessary.

Please contact us on 0802-492900 if you have any queries or you require further information.

Yours sincerely,