

“B 663” IN THE TREATMENT OF LEPROSY  
SUPPLEMENTARY REPORT OF THE  
PILOT TRIAL

By S. G. BROWNE, M.D., F.R.C.P., F.R.C.S., D.T.M.  
and

L. M. HOGENZEIL, MED. DRS., LEYDEN  
*Leprosy Service Research Unit, Uzuakoli, Eastern Nigeria*

The report of the interim findings in a pilot trial of “B 663” (GEIGY S.A.) in this Unit (BROWNE and HOGENZEIL, 1962 (*a*)) is now completed by this supplementary report, which concerns the 16 patients who formed the subject of the previous communication, together with 12 patients who joined the trial subsequently. Dosage scales for the newly-admitted patients, all unselected and untreated, were of the same order as previously indicated; similar laboratory investigations were carried out on all patients.

**Treatment**

The groups referred to in the former report continued treatment as follows:

*Group 1:* The 3 patients, having received B 663 and standard doses of dapsone for 6 months, continued to receive dapsone alone. They were joined by seven additional patients, who followed the same régime.

*Group 2:* The first 3 patients, having received B 663 alone for six months, received thereafter standard doses of dapsone. The remaining 5 patients of this group, having received B 663 alone for 6 months, continued to receive B 663 alone for a further 6 months; they thereafter received standard doses of dapsone alone. Five additional patients joined the first 3 of this group, receiving B 663 alone for 6 months, and then dapsone alone.

*Group 3:* The 5 patients of this group, having received B 663 for 6 months, and ditophal (“Etisul” I.C.I.) for the first 3 months, received thereafter standard doses of dapsone.

**Clinical findings**

All the 12 patients newly admitted to treatment with B 663 for 6 months, either alone (5 patients) or with standard doses of dapsone (7 patients), made clinical progress similar to that of the patients in Groups 1 and 2 of the preliminary report. It is not possible to detect any definite differences in so short a time between those who had dapsone in addition to B 663 and those who did not.

The 5 patients who, having had 6 months’ treatment with B 663

alone, received the drug alone for a further 6 months, all continued to improve clinically, though somewhat slower than at first, there being a considerable volume of lepromatous infiltration to be absorbed.

No novel clinical observations were made during this further investigation, except that the ruddiness of the uninfiltreated and non-lepromatous skin appeared less intense than in the early months of the trial: this ruddiness, it may be surmised, might militate against the use of B 663 in lighter-skinned patients. No signs of toxicity developed.

### **Bacteriological findings**

The average reductions in the Bacterial Index in the various Groups are summarized as follows:

*Group 1* (standard dapsone, with B 663 for the first 6 months):

All 10 patients:	44%
The 3 patients in the original Group, who have now received dapsone alone for 12 months:	
After 6 months of dapsone alone:	50%
After 12 months of dapsone alone:	80%

*Group 2* (B 663 alone for 6 months):

All 13 patients:	37%
Three of the patients in the original Group, have now received dapsone alone for 12 months:	
After 6 months of dapsone alone:	58%
After 12 months of dapsone alone:	83%
The remaining 5 patients of the original Group, have now received B 663 alone for a further 6 months (making 12 months in all):	
After 6 months (of B 663 alone):	58%
After 12 months (of B 663 alone):	66%

*Group 3* (B 663 for 6 months, with ditophal in addition for the first 3 months, followed by standard dapsone alone):

After 6 months:	27%
After 12 months (i.e. 6 months of dapsone alone):	37%

The quasi-complete disappearance of morphologically normal forms of *M. leprae*, and the increase in the proportion of acid-fast debris not identifiable as bacilli, occurred rather more rapidly in patients receiving dapsone and B 663.

### **Apparent resistance**

The 5 patients who were receiving B 663 alone suddenly showed, towards the end of the 12 months course, a sudden increase in the Bacterial Index and a reappearance of morphologically normal bacilli. Details will be found in the accompanying paper (BROWNE and HOGERZEIL, 1962 (*h*)).

### Summary

The tentative opinions expressed in the preliminary report are confirmed: B 663 has a definite action in lepromatous leprosy, inducing clinical and bacteriological improvement.

Given alone for 12 months, B 663 appears to cause a form of drug resistance in *M. leprae*.

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### References

- BROWNE, S. G. and HOGERZEIL, L. M. (1962) (a) *Leprosy Rev.*, **33**, 6.  
BROWNE, S. G. and HOGERZEIL, L. M. (1962) (b) *Leprosy Rev.* **33**, 182.

N.B. In view of the high cost of manufacture (inherent in the complex chemical structure of the compound, the difficulty of separation of isomers, and the technical processes of micronization of the product) it is unlikely that the drug could ever be a serious rival to dapsone. It would appear, however, that B 663 could be of value as a second line of defence and for use in patients who for some reason cannot tolerate dapsone. Further research in this promising line of compounds is therefore indicated.