

TGA **THERAPEUTIC
GOODS
ADMINISTRATION**

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241



Commonwealth Department of
**Health and
Aged Care**

File Number: 2001/014895
App. Number: 99/2436/1
31 May 2001

The Director
TGAL

APPLICATION FOR REGISTRATION - CATEGORY 1

PRODUCT: TRILEPTAL (Oxcarbazepine 60 mg/mL) ORAL SUSPENSION
MANUFACTURER: NOVARTIS PHARMA S.A.
26 RUE DE LA CHAPELLE
HUNINGUE (HAUT-RHIN)
FRANCE
APPLICANT: NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD
54 WATERLOO ROAD
NORTH RYDE NSW 2113

EVALUATION OF MICROBIOLOGICAL ASPECTS

[REDACTED]

supplied in a standard brown glass bottle with a child resistant polypropylene cap, with secondary packaging including a 10mL graduated polypropylene oral dispenser and LDPE bottle adaptor. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



