

The Co-ordination Unit Drug Safety & Evaluation Branch Therapeutic Goods Administration PO Box 100 Woden ACT 2606 24 February, 1998

Our ref: SC:lb98.33C

RECEIVED

0 2 MAR 1998

Drug Safety and Evaluation Branch

Dear Sir,

Re:

IMDUR (isosorbide mononitrate) 120 mg Durules - AUST R 62795

Date of Supply / Product Information

Application No: 97/098/3

A. 24

Further to TGA's approval letter dated 2 February 1998 regarding our application to register IMDUR (isosorbide mononitrate) 120 mg Durules (AUST R 62795), we wish to advise that the anticipated date of supply of IMDUR 120 mg Durules is **1 August 1998**.

Two copies of the final printed Product Information document for IMDUR are enclosed, as requested.

Please feel free to contact me should you have any queries.

Michael -97/453:

Yours faithfully, ASTRA PHARMACEUTICALS PTY LTD

SENIOR REGULATORY AFFAIRS ASSOCIATE

Encl.

COMPUTER UPDATED

Date: 4/5/98

App. No. 97. 098.3

WTAID: wfasma

Please R/s files for to August.

Then ring Company & confin

EXACT supply dark

Action PI's as per SOP's

Update dard Supply

Commonth outy

96 3/3/98