

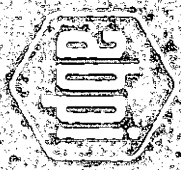
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COMPENDIUM  
of  
DATA SHEETS  
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Characteristics



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**ABPI COMPENDIUM OF DATA SHEETS  
AND  
SUMMARIES OF PRODUCT CHARACTERISTICS  
1998-99**

**With The Code of Practice for the  
Pharmaceutical Industry**

 **Datafarm Publications Limited  
12 Whitehall, London SW1A 2DY**

#### Responsibility for Data Sheets and Summaries of Product Characteristics

The data sheets and summaries of product characteristics in this Compendium are prepared independently by each participating company and each proof is checked and the text confirmed as correct by the participant concerned. Neither Datapharm Publications Limited nor The Association of the British Pharmaceutical Industry (ABPI) gives any guarantee whatsoever as to the accuracy of the information contained in the data sheets or summaries of product characteristics and accepts no liability whatsoever, in respect of any loss, damage or expense arising from any such information or for any error or omission in the data sheets or summaries of product characteristics and in particular (but without prejudice to the generality of the foregoing) shall not be liable for any consequential damages or expenses or any loss of profit or any liability to third parties incurred by anyone relying on the information contained in the data sheets and summaries of product characteristics appearing in this Compendium.

## THE COMPENDIUM

This is the second edition of the Compendium in which summaries of product characteristics (SPCs) appear. New requirements came into effect in 1999 replacing data sheets with SPCs for new products and those products coming up for licence renewal. There will be a period of about five years during which data sheets will coexist with SPCs and this edition of the Compendium reflects that fact.

Both data sheets and SPCs are prepared by the individual companies concerned and, in consequence, vary somewhat. In style, but all follow either the requirements laid down by The Medicines (Data Sheet) Regulations 1972 (for data sheets) or the European Commission's Committee for Proprietary Medicinal Products (CPMP) Note for Guidance (for SPCs).

Participation in the Compendium is open to all companies supplying medicinal products intended for use under medical supervision.

Data sheets and SPCs are intended for members of the medical and pharmaceutical professions and are written with them in mind. Any member of the public who reads them should bear in mind the need to take professional advice before making any decision affecting his or her own medication based upon their contents.

#### DATE OF PREPARATION

The data sheets included in this Compendium were finalised during the third quarter of 1997 and the Compendium itself was published in January 1998. Summaries of product characteristics have individual dates of approval/revision.

#### REVISED DATA SHEETS/SPCs

Individual participating companies may issue loose leaf data sheets/summaries of product characteristics (SPCs) which supersede those included in this Compendium.

It is advisable to retain any such revised data sheets/SPCs which are received and to indicate that fact on the corresponding data sheets or SPCs in the Compendium.

#### LEGAL CATEGORY

The following abbreviations are used under the heading 'Legal category' in data sheets and summaries of product characteristics in the Compendium.

- GSL. A preparation which is included in the General Sale List.
- P. A pharmacy sale medicine which can be sold only from a retail pharmacy.
- POM. A prescription only medicine.
- CD. A preparation controlled by the Misuse of Drugs Act 1971 and

Regulations. The CD is followed by (Sch 1), (Sch 2), (Sch 3), (Sch 4) or (Sch 5) depending on the schedule to the Misuse of Drugs Regulations 1985, as amended, in which the preparation is included.

*Doctors are reminded that certain of the particulars must be in their own handwriting on prescriptions for preparations coming within Schedule 2 and Schedule 3 (except phenobarbitone) to the Misuse of Drugs Regulations 1985, as amended.*

#### SYMBOLS AND ABBREVIATIONS

An asterisk (\*) by the name of a product indicates that the name is a trade mark. The company symbols which appear in certain participants' sections are also trade marks.

An inverted triangle (▼) by the name of a product indicates that that product is newly introduced and there

are special requirements as to the reporting of adverse reactions (see page iv)

OP in the 'Package quantities' section of a data sheet indicates that the pack is an 'original pack'.

#### FURTHER INFORMATION

The regulations which relate to data sheets restrict the scope of the material which may be given under the heading 'Further information' and require insertion of the word 'Nil' in any data sheet where there is no entry under that heading. Companies are, of course, none the less always willing to provide additional information on their products upon request.

Enquiries should be directed to the companies concerned. Addresses and telephone numbers are provided in the Directory of Participants in the coloured section at the end of the Compendium.

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...may increase the risk of hypotension, and cardiovascular emergency procedures should be available. The drug should be administered to patients with a known hypersensitivity to any of the components of the formulation. The drug should be administered to patients with a known hypersensitivity to any of the components of the formulation. The drug should be administered to patients with a known hypersensitivity to any of the components of the formulation.

**Pharmacokinetics:** The pharmacokinetics of Tenormin in patients with normal renal function are similar to those in patients with mild to moderate renal impairment. The drug is excreted primarily in the urine as the active metabolite, ZD 7288. The elimination half-life is approximately 12 hours. The drug is excreted primarily in the urine as the active metabolite, ZD 7288. The elimination half-life is approximately 12 hours.

**Pharmacodynamics:** Tenormin is a selective  $\alpha_1$ -adrenoceptor antagonist. It acts by blocking the action of adrenaline on the  $\alpha_1$ -adrenoceptor, thereby preventing the release of noradrenaline from the sympathetic nervous system. This results in a decrease in peripheral vascular resistance and a reduction in blood pressure.

**Contraindications:** Tenormin is contraindicated in patients with a known hypersensitivity to any of the components of the formulation. It is also contraindicated in patients with aortic stenosis, aortic regurgitation, or other forms of valvular disease. It should be used with caution in patients with renal impairment.

**Indications:** Tenormin is indicated for the treatment of essential hypertension. It may also be used in the treatment of benign prostatic hyperplasia. The drug is effective in reducing blood pressure and improving symptoms of benign prostatic hyperplasia.

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