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b) Patient information leaflet

The under-mentioned information with regard to this medicine shall appear on the patient information leaflet. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 10 of the Act).

1 Scheduling status
2 Proprietary name and dosage form
3 Composition of the medicine, that is, what this medicine contains
4 Approved indication and use, that is, what this medicine is used for
5 Instruction before taking the medicine
6 Instructions on how to take the medicine
7 Side effects
8 Storage and disposal information
9 Presentation
10 Identification
11 Registration number
12 Name and business address of the holder of the certificate of registration
13 Date of publication of the Patient Information Leaflet.

Please refer to the attached p 1C-10.

APPLICANT/PHCR:	*CIPLA-MEDPRO (PTY) LTD*	*DOSAGE FORM AND STRENGTH:*	*CAPSULE 100 mg DANOZOL PER CAPSULE*
PRODUCT PROPRIETARY NAME:	*DANOGEN 100*		

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Patient Information Leaflet

Information for the Patient about

DANOGEN 50 CAPSULES
DANOGEN 100 CAPSULES
DANOGEN 200 CAPSULES

Read all of this leaflet carefully before you start taking this medicine.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS:

Ref 1, pg1c-002

S4

PROPRIETARY NAME AND DOSAGE FORM:

DANOGEN 50 CAPSULES
DANOGEN 100 CAPSULES
DANOGEN 200 CAPSULES

Ref 1, pg 1c-002

WHAT DANOGEN 50/100 & 200 CAPSULES CONTAIN:

The active substance is danazol. DANOGEN 50/100 & 200 CAPSULES contain 50 mg /100 mg & 200 mg respectively.

Ref 1, pg 1c-002

Ref 2, pg 3B 1

WHAT DANOGEN 50/100 & 200 CAPSULES ARE USED FOR:

Ref 1,pg 1c-003

- DANOGEN 50/100 & 200 CAPSULES belong to a class of medicines called hormone inhibitors.

DANOGEN 50/100 & 200 are used for the treatment of the following:

- Endometriosis
- Severe cyclic breast pain and nodularity.
- For the prophylactic treatment of hereditary angioneurotic oedema, (cutaneous, abdominal and laryngeal) in both males and females.

Ref 1, pg 1c-003

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APPLICANT/PHCR:	*CIPLA-MEDPRO (PTY) LTD*	*DOSAGE FORM AND STRENGTH:*	*CAPSULE 100 mg DANOZOL PER CAPSULE*
PRODUCT PROPRIETARY NAME :	*DANOGEN 100*		

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BEFORE YOU USE DANOGEN 50/100 & 200 CAPSULES: Ref 1, pg 1c-003

Do not take DANOGEN 50/100 & 200 CAPSULES if you are/have:

- Pregnant women as danazol may have androgenic effect on the female fetus.
- Nursing mothers as it may have androgenic effect in the infant, both male (possible precocious sexual development) and female (virilization).
- Patient suffering from thrombo-embolic disorders.
- Patients with severe hepatic, cardiac or kidney dysfunction.
- Hypersensitivity to anabolic steroids, androgens and danazol.
- Porphyria.

Take special care with DANOGEN 50/100 & 200 CAPSULES: Ref 1, pg 1c-008

Tell your doctor if you have any of the following as you may then require a lower dose or special precautions:

- Migraine, epilepsy, cardiac and renal diseases
- Care should be used in patients with a history of thrombosis. Care should be exercised in patients with hepatic impairment. Ref 1. pg 1c-008
- Nephrotoxicity
- Diabetes

Taking DANOGEN 50/100 & 200 CAPSULES with food and drinks:

CAPSULES can be taken without regard to meals. Each capsule should be swallowed whole with fluid. Do not divide, crush, chew or place the CAPSULES in water. See **"HOW TO TAKE DANOGEN 50/100 & 200 CAPSULES"**. Ref 1, pg 1c-008

Use in pregnancy and breast feeding:

The safety of **DANOGEN 50/100 & 200 CAPSULES** in pregnancy and lactation has not been established. Thus use in pregnancy and lactation is not recommended. Ref1,pg 1c-004

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. Ref 3, pg 10

Use in children: Caution is recommended in children and adolescent being treated for hereditary angio oedema, because of possible androgenic effects and premature epiphyseal closure. Ref 1, pg 1c-005

Use in elderly:

No information is available on the effects of DANOGEN 50/100 & 200 CAPSULES in geriatric patients. In male patients there may be an increased risk of prostatic hypertrophy or prostatic carcinoma. — Ref 1, pg 1c-005

Can I drive or operate machinery while taking DANOGEN 50/100 & 200 CAPSULES?

DANOGEN 50/100 & 200 CAPSULES have not been shown to impair judgement, thinking or motor skills. Be cautious about operating hazardous machinery and driving until you are certain that the medicine does not affect them adversely.

Taking other medicines with DANOGEN 50/100 & 200 CAPSULES?

See "**BEFORE YOU TAKE DANOGEN 50/100 & 200 CAPSULES**"

If you are taking other medicines on a regular basis, use of this medicine with other medicines may cause undesirable interactions. — Ref1,pg 1c-004

Please consult your doctor or pharmacist.

Ref 3, pg 10

HOW TO TAKE DANOGEN 50/100 & 200 CAPSULES:

Always take DANOGEN 50/100 & 200 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Please consult your doctor before abruptly discontinuing DANOGEN 50/100 & 200 as your doctor will advise you on the tapered dose to minimise the risk of discontinuation symptoms. — Ref 3, pg10-11

If you take more DANOGEN 50/100 & 200 than you should:

In the event of an overdosage (if you take too many CAPSULES), or if someone else has taken your medicine by mistake, you, or this other person, may experience increased or decreased blood count, gastro-intestinal disturbances, dizziness, depression, headache, tremor, sleep disorders and nervousness. General and supportive measures are recommended. Contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre. — Ref 1, pg 1c-007

If you forget to take DANOGEN 50/100 & 200:

Take DANOGEN 50/100 & 200 as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

Ref 3, pg 11

Ref 3, pg 11

POSSIBLE SIDE-EFFECTS:

What undesirable effects may DANOGEN 50/100 & 200 have?

- DANOGEN 50/100 & 200 can have side-effects. As with any medicine, DANOGEN 50/100 & 200 may have unintended or undesirable effects.

Ref 1,pg 1c-006

- The most commonly observed adverse effects are:
  Dizziness, depression, headache, tremor, sleep disorders, nervousness, gastro-intestinal disturbances, increased or decreased blood count, acne, oily skin or hair and skin rash.
- The occurrence of many frequently observed adverse events is dose related. These generally decrease in intensity and frequency with continued therapy. Check with your doctor as soon as possible if the side-effects persist and become bothersome.

Ref 1, pg 1c-006

The following side-effects have been reported (≥ 1 % of patients):

Adverse effects are mainly androgenic and dose related and may include the following:

Body as a whole:

Less Frequent: Alopecia, backache, deepening of the voice

Gastrointestinal System Disorders:

Frequent: Gastro-intestinal disturbances

Ref 1,pg 1c-006

Cardiovascular System Disorders:

Frequent:	Hypertension, intracranial hypertension, tachycardia.	
Haematological and Lymphatic System Disorders:		
Frequent:	Increased or decreased blood count,	
Metabolic and nutritional:		
Frequent:	Hyper-glucagonaemia, abnormal glucose tolerance, decreased serum high-density-lipoprotein cholesterol, increased serum low-density-lipoprotein cholesterol, cholestatic jaundice, mild hirsutism, weight gain.	Ref 1,pg 1c-006
Musculoskeletal System Disorders:		
ess Frequent:	Muscle cramps and swelling of feet and lower legs,fatigue.	
Central nervous system:		
Frequent:	Dizziness, depression, headache, tremor, sleep disorders, nervousness.	Ref 1,pg 1c-006
Skin and appendages:		
Frequent:	Acne, oily skin or hair, skin rash,	
Special senses:		Ref 1,pg 1c-007
Frequent:	Visual disturbances.	
Urogenital System Disorders:		
Frequent:	Decreased breast size, spotting, irregular menstrual periods, breakthrough bleeding and weight gain, amenorrhoea, sweating, hot flushes, vaginitis, changes in libido and emotional lability have been reported, occasional clitoral hypertrophy, testicular atrophy, azoospermia.	Ref 1,pg 1c-007
Hepatic System Disorders:		

Less Frequent: Elevation of liver-function tests

Not all side-effects reported for this medicine are included in this leaflet. Ref 1,pg 1c-007

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE AND DISPOSING OF DANOGEN 50/100 & 200:

Store this medicine out of reach of children.

Store below 25°C. Ref 1,pg 1c-009

Keep the blister strips in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF DANOGEN 50/100 & 200:

DANOGEN 50: Blister pack with 10 capsules packed in 60's (6 x 10 Capsules).

Ref 1,pg 1c-009

DANOGEN 100: Blister pack with 10 capsules packed in 60's (6 x 10 Capsules).

DANOGEN 200: Blister pack with 10 capsules packed in 60's (6 x 10 Capsules).

IDENTIFICATION OF DANOGEN 50/100 & 200:

DANOGEN 50:

Dark green coloured oblong hard gelatin capsules with 'DGN'/50 printed straight in white on both halves. Capsule size 2.The capsule is filled with off-white to pale yellow powder. Ref 1,pg 1c-008

DANOGEN 100:

White coloured oblong hard gelatin capsules with 'DGN'/100 printed straight in white on both halves. Capsule size 2.The capsule is filled with off-white to pale yellow powder.

DANOGEN 200:

Scarlet red coloured oblong hard gelatin capsules with 'DGN'/200 printed

straight in white on both halves. Capsule size 1 The capsule is filled with of white to pale yellow powder.

REGISTRATION NUMBER:

To be allocated.

Ref 1,pg 1c-009

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park, Bellville

7530

Ref 1,pg 1c-009

DATE OF PUBLICATION OF THIS PATIENT LEAFLET:

Ref 1,pg 1c-009

2006 -01- 11

APPLICANT/PHCR:	*CIPLA-MEDPRO (PTY) LTD*	*DOSAGE FORM AND STRENGTH:*	*CAPSULE 100 mg DANOZOL PER CAPSULE*
PRODUCT PROPRIETARY NAME :	*DANOGEN 100*		

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REFERENCES TO PATIENT INFORMATION LEAFLET

REFERENCES	MRF1 PAGES
1. Proposed PI initially submitted by CIPLA-MEDPRO (PTY) LTD	1C-002
2. MRF 1, Part 3B – Formulation	3B-001
3. Guideline on the requirements for patient information leaflets, May 2004	