

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

Pr **CYCLOMEN**<sup>®</sup>  
(danazol capsules, USP)

**This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CYCLOMEN. Contact your doctor or pharmacist if you have any questions about the drug.**

#### ABOUT THIS MEDICATION

##### What the medication is used for:

- treatment of endometriosis
- relief of severe pain and tenderness associated with fibrocystic breast disease

##### What it does:

The lining of the uterus is called the endometrium. Part of it is shed during your menstrual period (period). In endometriosis, endometrium-like tissue is found outside the uterus, such as around the uterus, ovaries, intestines and other organs in the pelvis. As with normal endometrial tissue, this tissue can be shed during your period. Some women with endometriosis have symptoms such as painful periods, pelvic pain, pain during intercourse and painful bowel movements.

When used to treat endometriosis, CYCLOMEN changes the endometrium so that it becomes inactive and shrinks in size. Relief from painful symptoms usually begins a few weeks after starting CYCLOMEN.

When used to treat benign fibrocystic breast disease, CYCLOMEN relieves pain and tenderness in the breast and may also cause nodules in the breast to shrink. Pain and tenderness should begin to disappear after about 1 month. Nodules do not start to shrink in size until after 2 - 3 months of treatment.

After starting with CYCLOMEN you will probably have one more period. Your periods will then stop while you are taking CYCLOMEN, however, you may have occasional spotting or vaginal bleeding. After you stop taking CYCLOMEN your periods will start again, usually within 2 - 3 months.

##### When it should not be used:

CYCLOMEN should not be used if you:

- have abnormal vaginal bleeding, not diagnosed by your doctor
- have genital or breast tumors
- have liver, kidney or heart problems
- are pregnant
- are breastfeeding
- have porphyria
- have an androgen (male sex hormone) - dependent tumor
- have a tendency to form blood clots, or problems (past or current) with blood clots forming in your blood vessels
- have a known allergy to CYCLOMEN or any of its nonmedicinal ingredients (see below)
- are taking a medicine called simvastatin (used to treat high cholesterol).

##### What the medicinal ingredient is: Danazol

What the nonmedicinal ingredients are: Maize starch, red iron oxide (50 mg and 200 mg capsules), black iron oxide (100 mg capsules), yellow iron oxide (200 mg capsules), gelatin, lactose monohydrate, magnesium stearate, talc, titanium dioxide.

##### What dosage forms it comes in:

Capsules : 50 mg, 100 mg, 200 mg

#### WARNINGS AND PRECAUTIONS

- CYCLOMEN can cause harm to an unborn baby when given to pregnant women
- Use of CYCLOMEN to treat endometriosis may increase the risk of cancer of the ovaries or may induce tumors of the liver.

BEFORE you use CYCLOMEN talk to your doctor or pharmacist if you have:

- liver, kidney or heart disease
- high blood pressure
- atherosclerosis (hardening of the arteries)
- diabetes
- epilepsy
- blood clots
- suffer from migraines
- had an organ transplant
- recently undergone surgery

Talk to your doctor if you are experiencing any of the following symptoms with CYCLOMEN:

- development of male characteristics (virilization) such as deepening of the voice,

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- growth of body hair, clitoral thickening. In rare cases, these effects may not be reversible.
- headache or changes in vision due to an increase fluid pressure within the skull.
  - yellowing of the skin or eye (jaundice), loss of appetite, nausea, vomiting, fever, feeling unwell, unusual tiredness, itching, unusual darkening of the urine, right upper stomach area pain or discomfort. CYCLOMEN may cause liver problems, including life-threatening liver failure.
  - a blood clot in the leg (pain and swelling of the calf), or in the lung (sharp pain in the chest, coughing blood, or sudden shortness of breath)

### INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with CYCLOMEN include:

- coumadin (warfarin)-type anticoagulants (used to prevent blood clots from forming)
- carbamazepine, phenytoin and phenobarbital (drugs used to treat epilepsy)
- cyclosporin and tacrolimus (used to reduce organ rejection after an organ transplant operation)
- insulin or oral hypoglycemic agents (used to treat diabetes)
- anti-hypertensive drugs (used to treat high blood pressure)
- statin drugs (used to lower blood cholesterol such as simvastatin, atorvastatin and lovastatin).

The concomitant administration of CYCLOMEN with simvastatin is contraindicated.

### PROPER USE OF THIS MEDICATION

#### Usual Dose:

Treatment with CYCLOMEN should be uninterrupted, with no missed doses to be effective. CYCLOMEN should be started during your period. It is important that you use a non-hormonal method of contraception (such as diaphragm with contraceptive jelly, IUD, condoms) while taking CYCLOMEN.

*Endometriosis:* The usual total dose is 200 to 800 mg a day. This is given in 2 - 4 divided doses a day for 3 to 6 months. For severe cases, the starting dose is 800 mg a day. The maximum recommended dose is 800 mg a day.

*Fibrocystic Breast Disease:* The usual total dose is 100 - 400 mg a day. This is given in 2 doses a day for 6 months.

After stopping CYCLOMEN, if your symptoms return, talk to your doctor, you may be able to start treatment again.

#### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

#### Missed Dose:

If you miss a dose of CYCLOMEN, you should take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

CYCLOMEN causes changes to your body's normal sex hormone levels, as a result, you may notice the following side effects: acne, edema (swelling, especially of the hands, feet, and face), mild growth of body hair, decrease in breast size, deepening of the voice, oiliness of the skin or hair, weight gain, increase in size of the clitoris, flushing, sweating, vaginal itching and dryness, vaginal burning, vaginal spotting or bleeding, nervousness, mood changes, visual hallucinations or disturbances, and seizures.

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Other rare side effects are: jaundice (yellowing of the skin), liver tumors, liver and pancreatic disorders, rashes.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
<b>Rare</b>			
Nervous system disorders: Persistent headache		✓	
Gastrointestinal disorders: Pancreatic disorders (persistent abdominal pain)		✓	
<b>Very Rare</b>			
Pulmonary disorders: Pneumonia	✓		
Skin and subcutaneous tissue disorders: Severe skin rash	✓		
Blood and lymphatic disorders: Persistent abdominal pain		✓	
<b>Unknown frequency</b>			
Liver injury with symptoms such as: loss of appetite, nausea, vomiting, fever, feeling unwell, unusual tiredness, itching, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, right upper stomach area pain or discomfort.		✓	

*This is not a complete list of side effects. For any unexpected effects while taking CYCLOMEN, contact your doctor or pharmacist.*

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at:  
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program

Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**HOW TO STORE IT**

CYCLOMEN should be stored in a safe place at room temperature (15-30<sup>0</sup> C).

Keep out of the reach of children.

**MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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