

PART III: CONSUMER INFORMATION

Pr **ASPEN-DIENOGEST**

dienogest

This leaflet is Part 3 of a three-part "Product Monograph" published when ASPEN-DIENOGEST was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ASPEN-DIENOGEST. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ASPEN-DIENOGEST is a treatment for the painful symptoms caused by endometriosis in women who have had the first menstrual cycle (menarche).

What it does:

ASPEN-DIENOGEST works to help reduce pelvic pain associated with endometriosis (endometrium-like tissues outside the uterus which cause a chronic inflammation).

When it should not be used:

You should not use ASPEN-DIENOGEST if you:

- are pregnant
- are breastfeeding
- are suffering from a medical condition related to a blood clot (thromboembolic disorder). This may occur, for example, in the blood vessels of the legs (deep vein thrombosis) or the lungs (pulmonary embolism).
- have or have ever had a disease affecting the arteries, including cardiovascular disease, such as a heart attack, stroke, or heart disease which causes a reduced blood supply (angina pectoris)
- have diabetes with blood vessel damage
- have or have ever had severe liver disease (and your liver function values have not returned to normal). Symptoms of liver disease may be yellowing of the skin and/or itching of the whole body.
- have or have ever had a benign or malignant liver tumor
- have ever suffered from a malignant tumor such as cancer of the breast or the reproductive organs
- have any unexplained vaginal bleeding
- loss of vision due to blood vessel disease of the eye
- migraine headache

- are allergic to dienogest or any of the other ingredients of ASPEN-DIENOGEST (see **What the medicinal ingredient is** and **What the nonmedicinal ingredients are**)

If any of these conditions appear for the first time while you are using ASPEN-DIENOGEST, stop taking it at once and consult your doctor.

What the medicinal ingredient is:

dienogest

What the nonmedicinal ingredients are:

Cottonseed oil, hydroxypropylcellulose, hypromellose, lactose monohydrate, magnesium stearate, maize starch, povidone K 30, sodium starch glycolate (Type A), talc and titanium dioxide.

What dosage forms it comes in:

ASPEN-DIENOGEST is available in blister packs of 28 tablets.

ASPEN-DIENOGEST (dienogest) is available as white, round, biconvex film-coated tablets, embossed with "2" on one side.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ASPEN-DIENOGEST can decrease the bone mineral density (BMD) in adolescent girls (12 to < 18years). This effect may not be completely reversible once treatment is stopped.

Effects on BMD may be greater with increasing duration of use. It is unknown if the use of ASPEN-DIENOGEST during adolescence will reduce peak bone mass and increase the risk of developing osteoporosis (brittle bones).

The risks and benefits of this treatment in adolescents should be re-evaluated on a regular basis.

Before starting ASPEN-DIENOGEST, you must be sure that you are not pregnant and must stop taking any form of birth control that contains hormones such as the pill, patch, intrauterine system, injection, or ring.

While using ASPEN-DIENOGEST you must use a nonhormonal birth control method such as condoms or a diaphragm. DO NOT use any form of birth control that contains hormones.

ASPEN-DIENOGEST is not a birth control method and will not prevent pregnancy.

ASPEN-DIENOGEST should not be used in women who have not had their first menstrual cycle.

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. Smoking may also increase adverse effects on bone density. You should not smoke while taking ASPEN-DIENOGEST.

BEFORE you use ASPEN-DIENOGEST, talk to your doctor or pharmacist if you:

- have ever had a medical condition related to a blood clot (thromboembolic disorder) or anyone in your immediate family has had a blood clot at a relatively early age
- have a close relative who has had breast cancer
- suffer or have suffered from depression
- have uncontrolled high blood pressure
- have a history of liver disease. Symptoms may include yellowing of the skin or eyes or itching all over your body. Inform your doctor also if such symptoms occurred during a previous pregnancy.
- have diabetes or had diabetes temporarily during a previous pregnancy
- have ever had chloasma (golden-brown patches on the skin, particularly on the face)
- have lactose intolerance. ASPEN-DIENOGEST tablets contain lactose.

The Risks of Using ASPEN-DIENOGEST

1. Circulatory Disorder (including blood clots in the legs, lungs, heart, eyes, or brain)

Some studies have suggested that women who use progestin-only medications might have a slightly higher risk of blood clots; however, the results are not certain. You should discuss risk factors for blood clots with your doctor.

Be alert for the following symptoms and signs of serious adverse effects associated with blood clots. Call your doctor immediately if they occur:

- Sharp pain in the chest, coughing blood, or sudden shortness of breath.
- Pain and/or swelling in the calf.
- Crushing chest pain or heaviness.
- Sudden, severe, or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg.
- Sudden partial or complete loss of vision.

2. Breast Cancer

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include onset of menstrual periods before age 12 years, never having children, having your first full-term pregnancy after the age of 30 years, never having breastfed a child, and daily alcohol consumption.

Some studies have shown that the risk of developing breast cancer does not appear to be increased by using progestin-only therapies like ASPEN-DIENOGEST. However, more thorough studies are needed to confirm that there is no increased risk. You should also discuss breast self-examination with your doctor and report any breast lumps. A yearly breast examination by a health care professional is recommended for all women.

3. Diabetes

Patients with diabetes who use ASPEN-DIENOGEST should have their blood glucose levels closely monitored.

4. Ectopic Pregnancy

If you become pregnant while taking ASPEN-DIENOGEST, you are at a slightly increased risk of having an ectopic pregnancy (the embryo develops outside the womb). Before you start taking ASPEN-DIENOGEST, tell your doctor if you had an ectopic pregnancy in the past or have an impaired function of the fallopian tubes.

5. Liver Tumors

In rare cases, benign liver tumors, and in even fewer cases malignant liver tumors, have been reported in women taking hormones. Contact your doctor if you have unusually severe stomach pain.

6. Changes in Bone Mineral Density

The long-term use of ASPEN-DIENOGEST may decrease the bone mineral density of adolescents (12 to < 18 years) and, therefore, your doctor will carefully weigh the benefits of using ASPEN-DIENOGEST against other potential risks for bone loss. Your doctor may decide that your bone mineral density should be monitored.

If you use ASPEN-DIENOGEST, it will help your bones if you engage in regular weight-bearing exercise and have a healthy diet, including an adequate intake of calcium (e.g. in dairy products) and vitamin D (e.g. in oily fish such as salmon).

INTERACTIONS WITH THIS MEDICATION

Some medicines may interact with ASPEN-DIENOGEST. Let your healthcare professional know what other medicines you are taking.

Drugs that may interact with ASPEN-DIENOGEST include:

- Antifungals (eg, ketoconazole, itraconazole, fluconazole, voriconazole),
- Antibiotics (eg, erythromycin, clarithromycin, rifampicin)
- Anticonvulsants (eg, phenytoin, primidone, carbamazepine)
- Antacids (eg, cimetidine, ranitidine)
- Blood pressure medication (eg, diltiazem, verapamil)
- Drugs used for the treatment of HIV/Hepatitis C Virus infections (eg, ritonavir, saquinavir, indinavir, nelfinavir, boceprevir)

Herbal or food products that may interact with ASPEN-DIENOGEST include:

- St. John's wort
- Grapefruit juice

See also **ABOUT THIS MEDICATION**: When it should not be used, and **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**.

PROPER USE OF THIS MEDICATION

Usual dose

One tablet should be swallowed daily, preferably at the same time, with some liquid as needed. ASPEN-DIENOGEST can be taken with or without food.

Overdose

If you think you have taken too much ASPEN-DIENOGEST, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose

ASPEN-DIENOGEST will be less effective if you miss a tablet or have vomiting or diarrhea. If you miss one or more tablets or in case of vomiting or diarrhea within 3-4 hours of taking a tablet, take a tablet as soon as you remember and then continue taking the tablet the next day at your usual time. Do not take more than one tablet per day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ASPEN-DIENOGEST can cause side effects. These effects are more common during the first months after you start ASPEN-DIENOGEST and usually disappear or lessen with continued use. You may also experience changes in your menstrual bleeding pattern, such as spotting, irregular

bleeding, or your periods may stop completely. You should consult your physician if your periods become longer or heavier.

Common (may affect up to 1 in 10 users)

- weight gain
- depressed mood, problems sleeping, nervousness, or loss of interest in sex
- headache or migraine
- nausea or abdominal pain
- acne or hair loss
- breast discomfort
- ovarian cyst
- uterine/vaginal bleeding including spotting
- generalized weakness
- irritability

Uncommon (may affect up to 1 in 100 users)

- increase in appetite
- anxiety, depression, changed mood, or mood swings
- disturbed attention
- dry eyes
- ringing in the ears
- palpitations
- diarrhea, constipation, abdominal discomfort, gas, vomiting, inflammation of the stomach and intestines
- dry skin, severe itching of the whole body, brittle nails, dermatitis, light sensitivity or problems with skin pigmentation
- pains in your bones, back pain, muscle spasms, pains and/or a sensation of heaviness in your arms and hands or legs and feet
- urinary tract infection
- vaginal yeast infection, dryness of the genital area, vaginal discharge, pelvic pain, hot flushes, or a lump or lumps in the breast
- swelling due to fluid retention

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical treatment
		Only if severe	In all cases	
Common	Abdominal pain or nausea		✓	
	Unexpected vaginal bleeding		✓	
Uncommon	Persistent sad mood		✓	
	Breast lump		✓	
	Vomiting		✓	
Rare	Pain or swelling in the leg			✓
	Unusual swelling of the extremities			✓

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

HOW TO STORE IT

Store ASPEN-DIENOGEST in the original packaging between 15°C and 25°C. Keep out of reach of children and pets.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about ASPEN-Dienogest:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213

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Last Revised: January 02, 2025