

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION  
PATIENT MEDICATION INFORMATION**

**Pr DIANE®-35**

Cyproterone acetate and ethinyl estradiol tablets

Read this carefully before you start taking **DIANE-35** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DIANE-35**.

**Serious Warnings and Precautions**

- Do not use DIANE-35 if you have, or have ever had, a blood clot or redness, pain or swelling in your veins. It could have been in the leg, lung, or other part of your body.
- Women who use DIANE-35 appear to have a higher risk of blood clots than women who use levonorgestrel-containing birth control pills. The risk of blood clots with DIANE-35 appears to be similar to the risk with birth control pills that contain desogestrel and drospirenone. In rare cases, blood clots can lead to death.
- Do not use other estrogens or progestogens (alone or in combination) when taking DIANE-35.
- Do not use DIANE-35 for the purpose of birth control alone.
- Your doctor will tell you how long you need to keep taking DIANE-35. It should be stopped 3 to 4 months after signs have completely resolved.
- Smoking increases the risk of serious side effects on the heart and blood vessels. This occurs in women who use DIANE-35 or estrogen/progestogen combinations. Women who use DIANE-35 should not smoke.

**Do not use DIANE-35 if you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C. Using these drugs at the same time as DIANE-35 has the potential to cause liver problems, such as an increase in the ALT liver enzyme. You can usually start DIANE-35 about 2 weeks after finishing treatment with this combination of drugs used for Hepatitis C, but always consult with your doctor or pharmacist.**

**What is DIANE-35 used for?**

DIANE-35 is used to treat women with severe acne along with seborrhea or mild hirsutism. Mild hirsutism is excess hair on the face, chest, abdomen or legs. Seborrhea is a condition associated with excess oily secretions of the skin. It causes scaly, flaky, itchy, and red skin.

DIANE-35 should only be used when acne does not respond to other treatments. These include treatments that are put on the skin and oral antibiotics.

**How does DIANE-35 work?**

DIANE-35 reduces the activity of the oil-producing skin glands. They play an important role in the development of acne. Treatment with DIANE-35 can lead to the healing or improvement of existing acne. This occurs within 3 to 6 months of starting therapy.

## **What are the ingredients in DIANE-35?**

DIANE-35 contains a progestogen called cyproterone acetate and an estrogen called ethinyl estradiol.

Non-medicinal ingredients: calcium carbonate, corn starch, ferric oxide yellow, glycerol, lactose, magnesium stearate, polyethylene glycol, povidone, sucrose, talc, titanium dioxide and wax.

## **DIANE-35 comes in the following dosage form:**

Tablets: 2 mg cyproterone acetate and 0.035 mg ethinyl estradiol

## **Do not use DIANE-35 if you have or have had any of the following conditions:**

- blood clots in the legs, lungs, eyes or another part of the body, or inflammation of the veins (thrombophlebitis)
- problems with your blood clotting system that increase your risk of developing blood clots or if they have occurred in close relatives
- a stroke, or mini-stroke
- a heart attack, angina, heart or coronary artery disease
- disease of the heart valves with complications
- uncontrolled blood pressure
- severe migraine headaches or a history of them. Symptoms can include speech disability or weakness or numbness in any part of your body
- yellowing of your eyes or skin (jaundice)
- liver disease
- liver tumour
- you are taking ombitasvir, paritaprevir, ritonavir, with or without dasabuvir for the treatment of Hepatitis C
- a known or suspected cancer. It can be of the breast, uterus or ovaries. It can be a cancer that grows in response to estrogen
- a known or suspected hormone-dependent disorder
- severe diabetes associated with problems of the blood vessels
- unusual vaginal bleeding without a known reason
- a loss of vision due to blood vessel disease of the eye
- deafness that got worse during a pregnancy
- you are using an estrogen/progestogen combination, or an estrogen, or a progestogen alone
- are pregnant or think you might be pregnant
- you are breastfeeding. DIANE-35 passes into breast milk. It may decrease quality and flow
- allergy to cyproterone acetate, ethinyl estradiol, or to any of the other ingredients in DIANE-35

## **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DIANE-35. Talk about any health conditions or problems you may have, including if you:**

- smoke
- smoke more than 15 cigarettes a day and are over age 35. Your doctor may decide on a different treatment for you
- are overweight
- have a history of breast disease (eg, breast lumps) or a family history of breast cancer
- have an immediate family member who has ever had a blood clot (in the leg, lung or other parts of the body), a heart attack or a stroke at a young age
- have high blood pressure, or a family history of it

- have high cholesterol or if someone in your immediate family has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- have diabetes, or a family history of it
- suffer from migraines (headaches with symptoms such as disturbed vision or nausea)
- have heart or kidney disease
- have a history of liver disease
- have a history of jaundice (yellowing of the skin or eyes), especially if this happened during pregnancy
- have a history of seizures/epilepsy
- asthma or difficulty breathing
- fluid retention (such as swelling of lower legs)
- have a history of depression (sad mood that won't go away)
- wear contact lenses. If you wear contact lenses and develop visual changes or changes in lens tolerance, you should see an ophthalmologist. Temporary or permanent discontinuation of contact lens use should be considered
- are near-sighted or have astigmatism. Estrogen/progestogen combinations can make these problems worse, especially in women who have a family history of myopia
- have uterine fibroids (non-cancerous growths of the uterus)
- have systemic lupus erythematosus, a disease where the immune system injures the body's own organs and tissues. In some women, the use of estrogen/progestogen combinations may lead to worsening of joint and muscle pain
- have an inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- may be pregnant or are breastfeeding
- have any problems with the valves in your heart and/or have an irregular heart rhythm
- have golden brown pigment patches sometimes called 'pregnancy patches' especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light
- have polycystic ovary syndrome (a disorder where many small cysts grow on the ovary and may cause irregular menstrual periods, infertility, acne or excess hair growth. This disorder may increase the risk of blood clots)
- have been told that you have a condition called hereditary angioedema or if you have had episodes of swelling in body parts such as hands, feet, face, or airway passages
- menstrual periods that are light or that occur in an irregular pattern
- have a scheduled lab test or surgery. Consult your doctor about stopping DIANE-35. It should be stopped for four weeks before surgery. After surgery, wait until you have a full menstrual period before re-starting DIANE-35.

**Other warnings you should know about:**

You should not take DIANE-35 for the purpose of birth control alone. If you take it as directed, it will provide reliable birth control. You should not use other hormonal birth control methods when on DIANE-35. If you miss a dose of DIANE-35, use a non-hormonal birth control to prevent pregnancy.

Do NOT take DIANE-35 if you are obese and have high blood pressure, and diabetes. This combination is particularly hazardous. Your doctor should prescribe a different acne treatment for you.

DIANE-35 should only be used in women older than 35 in exceptional cases. You and your doctor must decide that the benefits are greater than the risks. You should know that the risk of serious side effects goes up after age 35. You will need to use DIANE-35 for a shorter amount of time. You should be seen regularly by the doctor. In addition, you should not smoke.

## **Breast Cancer**

**Cancer of the breast may be life-threatening or may result in death.**

The risk of breast cancer goes up with:

- increasing age
- strong family history of breast cancer (mother or sister)
- obesity
- never having children
- having your first full-term pregnancy at a late age
- use of drugs that contain estrogen/progestogen combinations such as DIANE-35 for more than 8 years
- using estrogen/progestogen combination drugs at an early age

The risk of breast tumors gradually goes down after stopping the combined pills.

A yearly breast examination by a healthcare professional is recommended. Talk to your doctor about breast self-examination. Tell your doctor right away if you find a new lump or mass.

## **Liver Cancer**

**Cancer of the liver may be life-threatening or may result in death.**

Tumors caused by cancer and other reasons can occur. These have led to life-threatening internal bleeding. Contact your doctor immediately if you have severe pain or a lump in your abdomen.

## **Pregnancy**

You should NOT use DIANE-35 if you are pregnant or think that you may be pregnant. It will not prevent the pregnancy from continuing. It may interfere with the normal development of your baby. If you become pregnant while taking DIANE-35, stop taking it immediately and contact your doctor.

## **Use after pregnancy, miscarriage or an abortion**

Talk to your doctor before using DIANE-35 after childbirth, miscarriage, or having an abortion.

## **Pregnancy after stopping DIANE-35**

If you wish to become pregnant, talk with your doctor. They may recommend that you stop using DIANE-35 and delay pregnancy until you have at least one period (menstrual cycle). Contact your doctor for advice and on methods of birth control that may be used during this time.

**Tell all healthcare professionals about all the medicines you take. This includes DIANE-35 and any other drugs, vitamins, minerals, natural supplements or alternative medicines.**

Certain drugs may interact with DIANE-35. They can make it less able to prevent pregnancy. Or, they can cause unexpected vaginal bleeding. Healthcare professionals can tell you if you need to use an additional method of birth control while using another medicine and if so, for how long.

**The following may interact with DIANE-35:**

- drugs used for the treatment of epilepsy (eg, carbamazepine, ethosuximide, lamotrigine, phenobarbital, phenytoin, primidone)
- drugs used for the treatment of tuberculosis (eg, rifampin)
- drugs used for the treatment of HIV infections (eg, nevirapine, ritonavir)
- drugs used for the treatment of Hepatitis C virus infections (eg, boceprevir, telaprevir)
- ombitasvir, paritprevir, ritonavir, with or without dasabuvir (used to treat Hepatitis C)
- antibiotics for bacterial infections such as penicillins, tetracyclines, ampicillin, cotrimoxazole, chloramphenicol, metronidazole, neomycin, nitrofurantoin, sulfonamides, and troleandomycin
- antifungals (for the treatment of fungal infections) (griseofulvin)
- anti-coagulants (blood thinners)
- antihypertensive drugs for high blood pressure (eg, guanethidine, methyldopa, beta blockers)
- antidiabetic drugs and insulin (for diabetes)
- antipyretics (eg, acetaminophen, antipyrine, ASA)
- prednisone
- cholesterol-lowering drugs (eg, clofibrate)
- sedatives and hypnotics (eg, barbituates, benzodiazepines, chloral hydrate, glutethimide, meprobamate)
- drugs used to treat upset stomach or heartburn (antacids) (use 2 hours before or after taking DIANE-35)
- drugs used to treat allergy (eg, antihistamines)
- drugs used to treat pain (eg, analgesics)
- drugs used to treat migraine (eg, antimigraine preparations)
- drugs used to treat sad mood (eg, clomipramine)
- drugs used to treat bleeding episodes in some people (eg, aminocaproic acid)
- drugs used to stop preterm labour (eg, beta mimetic agents)
- drugs used to treat schizophrenia (eg, phenothiazine tranquilizers)
- drugs used to treat symptoms of blocked airways (eg, theophylline)
- Vitamin E, Vitamin C, Vitamin B<sub>12</sub>, folic acid
- the herbal remedy St. John's wort (primarily used for the treatment of depression)
- alcohol
- caffeine

**How to take DIANE-35:**

Take DIANE-35 only on the advice of your doctor. You must take the tablets exactly as prescribed. If not taken appropriately, the contraceptive effect may be decreased and you may become pregnant. Your doctor may tell you to take a non-hormonal method of birth control while taking DIANE-35.

**Usual dose:**

Take one tablet at about the same time every day for 21 days. Swallow it whole with some liquid. Continue until the pack is empty. Do not take any medication for the next 7 days.

You must NOT be off the tablets for more than 7 days in a row.

***When to start the first pack of pills:***

Begin taking tablets on the first day of your period. Take a tablet marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked 'Fri'.

***Unscheduled period or spotting:***

During the month, if an "unscheduled" period occurs during the 3 weeks when you are taking DIANE-35 tablets, continue taking the tablets. Slight bleeding will usually stop on its own. If the bleeding is heavy, or similar to menstrual bleeding, talk to your doctor. Many women have spotting or light bleeding, or may feel sick to their stomach during the first three months on DIANE-35 therapy. If you feel sick, do not stop taking DIANE-35. The problem will usually go away. If it does not go away, check with your doctor or clinic.

***When you finish a pack:***

During the 7 tablet-free days, you should have your period. You will usually get your period 2-4 days after taking the last tablet.

***When to start the second and ongoing pack of pills:***

The first tablet in the next pack will always be taken on the same day of the week that you first began taking DIANE-35. Take this pill as scheduled regardless of whether your period is in progress.

***Missed Period:***

If bleeding does not occur during the 7 tablet-free days, do not start a new pack of DIANE-35. Contact your doctor to rule out pregnancy. To prevent pregnancy, another non-hormonal birth control method must be used.

***Length of Use:***

Your doctor will tell you how long to keep taking DIANE-35. This depends on how severe your symptoms are and how they respond to treatment. In general, treatment should be stopped 3 to 4 cycles after signs have completely resolved.

***Restarting DIANE-35:***

If symptoms return, weeks or months after you stop taking DIANE-35, treatment may be restarted by your doctor. Always follow the advice of your doctor. If it has been more than a 4 weeks without taking a DIANE-35 tablet, there is an increased risk for blood clots.

***Overdose:***

Symptoms of overdose may include nausea, vomiting, or vaginal bleeding. Even girls who have not yet had their first menstrual period but have accidentally taken this medicine may experience such bleeding.

If you think you have taken too much DIANE-35, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## **Missed Dose:**

### ***What to do if you miss tablets:***

If you miss tablets at any time, you could get pregnant. The greatest risks for pregnancy are:

- when you start a pack late, or
- when you miss tablets at the beginning or at the very end of the pack.

If you forget to take your tablet at the usual time, you must take it within the next 12 hours. If more than 12 hours have passed discard the missed tablet. Continue to take the remaining tablets in the pack at the usual time. This will prevent you from getting your period early. To prevent pregnancy, another non-hormonal birth control method must be used during this cycle.

### **Please note: pregnancy is most likely to occur when you have:**

- not taken DIANE-35 tablets on a regular basis
- vomiting or intestinal problems with diarrhea
- a very rare problem with your metabolism
- ongoing use of other certain drugs while taking DIANE-35

If you vomit or have diarrhea you must continue to take the rest of the tablets. To prevent pregnancy another non-hormonal birth control method must be used. This continues for the rest of the cycle.

### **What are possible side effects from using DIANE-35?**

These are not all the possible side effects you may feel when taking DIANE-35. If you experience any side effects not listed here, contact your healthcare professional. Please also see the box called “Serious Warnings and Precautions.”

Side effects in women taking DIANE-35 or estrogen/progestogen combinations may include:

- nausea and vomiting
- pain during your period
- symptoms similar to those you may have before your period such as mood changes or irritability
- changes in your sex drive
- breast tenderness, changes, enlargement, or discharge
- decrease in milk supply in women who are breastfeeding
- headache, dizziness
- nervousness
- development of golden brown patches on the face (chloasma)
- increase or decrease in weight and appetite
- runny or stuffy nose, or sneezing (rhinitis)
- the cervix is the opening of the womb. It can change with growth of tissue or produce vaginal secretions
- difficulty getting pregnant after stopping treatment

DIANE-35 can cause abnormal blood test, Papanicolaou (Pap) smear, breast examination, and urine test results. Your doctor will decide when to perform tests and interpret the results.

Visit your doctor three months or sooner after your first examination. Afterward, visit your doctor at regular intervals.

## SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/ effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Blood clot in the leg (deep vein thrombosis):</b> leg warmth, swelling or pain especially when standing or walking. You may have red or discoloured skin on your leg			✓
<b>Liver Cancer or Tumor:</b> severe abdominal pain, nausea, vomiting or lump in the abdomen		✓	
<b>Breast Cancer:</b> breast lumps		✓	
<b>Heart Attack:</b> gradual chest pain, tightness pressure or squeezing. Pain in the arm, jaw or back. Trouble breathing, anxiety, and sweating. Rapid or irregular heartbeat. Upset stomach or heartburn, choking feeling, nausea, and vomiting. Dizziness, and weakness			✓
<b>High blood pressure:</b> headache, vision disorders, nausea and vomiting			✓
<b>Allergic reaction:</b> Itching of the whole body. Or, rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
<b>Depression:</b> Sad mood that won't go away. If you have a history of depression, these drugs may make your depression worse			✓
<b>Blood clot in the lung (pulmonary embolism):</b> sharp chest pain that may increase with deep breathing, coughing up blood, or sudden shortness of breath, or rapid breathing. Anxiety, dizziness, rapid or irregular heartbeat			✓
<b>Blood clot in the eye:</b> Sudden partial or complete loss of vision			✓
<b>Stroke or blood clot in the brain:</b> Sudden severe headache, vomiting, confusion, loss of balance or coordination, sudden trouble walking, dizziness, fainting with or without seizure, problems with your vision or speech or understanding, weakness or numbness in the face, arm or leg especially on one side of the body			✓
Unexpected, irregular vaginal bleeding, lack of a period or bleeding between periods, especially if you also have secretions from your breast		✓	
<b>Edema:</b> Unusual swelling of the arms, hands, legs or feet, face or airway passages		✓	
<b>Jaundice or Hepatitis:</b> Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			✓

## SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/ effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Other signs of a blood clot can include:</b> sudden pain, swelling, and slight blue discoloration of your hands or feet; sudden, severe pain in your abdomen			✓
<b>UNKNOWN</b>			
<b>Severe Headache or Worsening of your Migraine Headaches</b>			✓
<b>Gallstones:</b> an attack often happens after a fatty meal. It may have intense pain in the upper abdomen, nausea, and vomiting	✓		
<b>Abdominal cramps and bloating</b>	✓		
<b>Increase in size of uterine leiomyomata</b> (non-cancerous growths in the wall of the uterus): increased abdominal pain and vaginal bleeding	✓		
<b>Reduced tolerance to carbohydrates</b> (increased blood sugar levels in diabetics or people who are at risk for diabetes): frequent urination, thirst and hunger	✓		
<b>Vaginal yeast infection, Vaginitis</b> (inflammation of the vagina): itching, burning, or discharge from the vagina		✓	
<b>Difficulty wearing contact lenses, change in the shape of your cornea, cataracts</b> (cloudy vision), <b>optic neuritis</b> (eye pain or changes in vision)	✓		
<b>Chorea:</b> abnormal or uncontrolled movements of the arms or legs		✓	
<b>Cystitis-like syndrome</b> (bladder infection): frequent or urgent urination, pain or burning when urinating, foul-smelling urine, cloudy or bloody urine		✓	
<b>Hirsutism:</b> excess hair on the face, chest, abdomen or legs	✓		
<b>Loss of scalp hair</b>	✓		
<b>Erythema multiforme:</b> skin reaction causing a rash or red lumps	✓		
<b>Erythema nodosum:</b> skin condition causing reddish, painful lumps, usually on the legs	✓		
<b>Hemorrhagic eruption</b> (bleeding under the skin): red or purple spots, or patches	✓		
<b>Porphyria</b> (a disease affecting the function of blood): confusion, severe abdominal pain, heart palpitations, trouble breathing, or red/brown urine	✓		
<b>Impaired kidney function:</b> mental confusion, fatigue, muscle cramps, increased urination, swelling of the ankles or feet		✓	

## SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/ effect	Talk with your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Raynaud's phenomenon</b> (reduced blood flow): discoloration of your fingers or toes	✓		
<b>Auditory disturbances:</b> changes in hearing		✓	
<b>Hemolytic uremic syndrome</b> (abnormal breakdown of the blood cells which can clog the kidney): bloody diarrhea or urine, vomiting, abdominal pain, fatigue, confusion, or swelling of the face, hands, or feet		✓	
<b>Pancreatitis</b> (inflammation of the pancreas): nausea, vomiting or abdominal pain		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### 3 ways to report:

- Online at [MedEffect](http://www.healthcanada.gc.ca/medeffect) (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

*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.*

### Storage

Store at room temperature (15°C - 25°C).

Keep out of reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines which are no longer required. These measures will help to protect the environment.

**If you want more information about DIANE-35:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website <http://www.bayer.ca> or by contacting Bayer at 1-800-265-7382.

This leaflet was prepared by:



Bayer Inc.  
2920 Matheson Boulevard East,  
Mississauga, Ontario  
L4W 5R6

Last Revised: March 16, 2017

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