

**PART III: CONSUMER INFORMATION**

**PrIndayo®**  
**(Levonorgestrel and Ethinyl Estradiol Tablets, USP)**  
**0.15 mg and 0.03 mg**

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Indayo is indicated for the prevention of pregnancy.

Indayo is a birth control pill (oral contraceptive) that contains two female sex hormones (levonorgestrel and ethinyl estradiol). It has been shown to be highly effective in preventing pregnancy when taken as prescribed by your doctor. Pregnancy is always more risky than taking birth control pills, except in smokers older than age 35.

Birth control pills work in two ways:

1. They inhibit the monthly release of an egg by the ovaries.
2. They change the mucus produced by the cervix. This slows the movement of the sperm through the mucus and through the uterus (womb).

**What You Should Know About Your Menstrual Cycle When Taking Indayo**

When you take Indayo, which has a 91-day treatment cycle, you should expect to have 4 menstrual periods per year (bleeding when you are taking the 7 white pills). However, you should expect to have more bleeding or spotting between your menstrual periods than if you were taking an oral contraceptive with a 28-day treatment cycle. During the first Indayo treatment cycle, about 1 in 3 women may have 20 or more days of unplanned bleeding or spotting (bleeding when you are taking pink pills). This bleeding or spotting tends to decrease during later cycles. Do not stop Indayo because of the bleeding. If the spotting continues for more than 7 consecutive

days or if the bleeding is heavy, call your healthcare professional.

**Effectiveness of Birth Control Pills**

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

A 99 percent effectiveness rate means that if 100 women used birth control pills for one year, one woman in the group would get pregnant.

The chance of becoming pregnant increases with incorrect use.

**Other Ways to Prevent Pregnancy**

Other methods of birth control are available to you. They are usually less effective than birth control pills. When used properly, however, other methods of birth control are effective enough for many women.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

**Reported Pregnancies per 100 Women per Year:**

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. (This does not apply to IUDs since they are implanted in the uterus). Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

The effective use of birth control methods other than birth control pills and IUDs requires more effort than taking a single pill every day. It is an effort that many couples undertake successfully.

**When it should not be used:**

The birth control pill is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of the birth control pill should always be supervised by your doctor.

You should not use Indayo if you have or have had any of the following conditions:

- blood clots in the legs, lungs, eyes, or elsewhere, or thrombophlebitis (inflammation of the veins)
- stroke, heart attack, or coronary artery disease (e.g. angina pectoris), or a condition that may be a first sign of a stroke (such as a transient ischemic attack or small reversible stroke)
- disease of the heart valves with complications
- severe high blood pressure
- diabetes with complications
- known abnormalities of the blood clotting system that increases your risk for developing blood clots
- very high blood cholesterol or triglyceride levels
- heavy smoking (>15 cigarettes per day) and over age 35
- migraine headache
- you are scheduled for major surgery
- prolonged bed rest
- jaundice (yellowing of the eyes or skin), liver disease or liver tumour
- known or suspected cancer of the breast or uterus (womb) or other estrogen-dependent cancer
- unusual vaginal bleeding without a known reason
- loss of vision due to blood vessel disease of the eye
- you are pregnant or suspect you may be pregnant
- pancreatitis (inflammation of the pancreas) associated with high levels of fatty substances in your blood
- allergy (hypersensitivity) to ethinyl estradiol, levonorgestrel or to any of the other ingredients in Indayo (see **What the medicinal ingredients are** and **What the non medicinal ingredients are**)

You should not be taking Indayo with hepatitis C drug combinations containing, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir. This may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood.

**What the medicinal ingredients are:**

Levonorgestrel and ethinyl estradiol

**What the important non medicinal ingredients are:**

Each active pink tablet contains the following non medicinal ingredients: lactose monohydrate, D&C Red No. 27, FD&C Blue No. 2, FD&C Yellow No. 5, magnesium stearate, polacrillin potassium and red iron oxide.

Each inert white tablet contains the following non medicinal ingredients: lactose monohydrate, magnesium stearate and polacrillin potassium.

**What dosage forms it comes in:**

Tablets. Indayo is used with a 91-day schedule (84 days of pink tablets followed by 7 days of white tablets).

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in hormonal contraceptive users older than 35 years of age. Women should not smoke.**

**Birth control pills DO NOT PROTECT against sexually transmitted diseases (STDs), including HIV/AIDS.**

**For protection against STDs, it is advisable to use latex condoms IN COMBINATION WITH birth control pills.**

**Use of Indayo provides women with more hormonal exposure on a yearly basis than conventional monthly oral contraceptives containing similar strength synthetic estrogens and progestins (9 additional weeks of hormonal exposure per year). While this added exposure may pose an additional risk of thrombotic and thromboembolic diseases, studies to date with Levonorgestrel and Ethinyl Estradiol Tablets have not suggested, nor can exclude, this additional risk.**

**Indayo Oral Contraceptive**

Indayo is a 91-day cyclic dosing regimen (84 days with active oral tablets of 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol, followed by 7 days with placebo tablets). Pregnancy should be ruled out in

cases of unanticipated bleeding/spotting, missed withdrawal bleeding/amenorrhea or signs and symptoms of pregnancy.

**BEFORE you use Indayo talk to your doctor or pharmacist if you:**

- smoke
- have a history of breast disease (e.g. breast lumps) or a family history of breast cancer
- have high blood pressure
- have high cholesterol
- have diabetes
- have heart or kidney disease
- have a history of seizures/epilepsy
- have a history of depression
- have a history of liver disease or jaundice
- wear contact lenses
- have uterine fibroids (benign tumours of the uterus)
- may be pregnant or are breast feeding
- have systemic lupus erythematosus
- have inflammatory bowel disease such as Crohn’s disease or ulcerative colitis
- have hemolytic uremic syndrome
- have sickle cell disease
- have any problems with the valves in your heart and/or have an irregular heart rhythm
- have been told that you have a condition called hereditary or acquired angioedema or if you have had episodes of swelling in body parts such as hands, feet, face or airway passages.

Skin pigmentation (brown patches on the skin) may occur with combination oral contraceptives including Indayo. Women developing brown patches should avoid exposure to the sun or ultraviolet radiation while taking Indayo.

You should also inform your doctor about a family history of blood clots, heart attacks, or strokes.

If you see a different doctor, inform him or her that you are using Indayo.

Tell your doctor if you are scheduled for any laboratory tests since certain blood tests may be affected by hormonal contraceptives.

Also tell your doctor if you are scheduled for **MAJOR** surgery. You should consult your doctor about stopping the use of Indayo four weeks before stopping the use of Indayo for a time period after surgery or during bed.

Indayo should be used only under the supervision of a doctor, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year. Use Indayo only on the advice of your doctor and carefully follow all directions given to you. You must use the birth control pill exactly as prescribed. Otherwise, you may become pregnant.

If you and your doctor decide that, for you, the benefits of Indayo outweigh the risks, you should be aware of the following:

**THE RISKS OF USING INDAYO**

**1. Circulatory disorders (including blood clot in legs, lungs, heart, eyes or brain)**

Blood clots are the most common serious side effects of birth control pills. The risk of developing blood clots is especially high during the first year a woman ever uses a hormonal contraceptive. Clots can occur in many parts of the body.

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

- sharp pain in the chest, coughing blood, or sudden shortness of breath. These symptoms could indicate a possible blood clot in the lung.
- pain and/or swelling in the calf. These symptoms could indicate a possible blood clot in the leg.
- crushing chest pain or heaviness. These symptoms could indicate a possible heart attack.
- sudden severe or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg. These symptoms could indicate a possible stroke.
- sudden partial or complete loss of vision. This symptom could indicate a blood clot in the eye.

Any of these conditions can cause death or disability. Clots also occur rarely in the blood vessels of the eye, resulting in blindness or impaired vision or in a blood vessel leading to an arm or leg, resulting in damage to or loss of a limb.

Women who use hormonal contraceptives have a higher incidence of blood clots. The risk of clotting seems to increase with higher estrogen doses. It is important, therefore, to use as low a dosage of estrogen as possible.

## 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 obesity, never having children, and having your first full-term pregnancy at a late age.

Some women who use hormonal contraceptives may be at increased risk of developing breast cancer before menopause, which occurs around age 50. These women may be long-term users of birth control pills (more than eight years) or women who start using birth control pills at an early age. In a few women, the use of birth control pills may accelerate the growth of an existing, but undiagnosed, breast cancer. Early diagnosis, however, can reduce the effect of breast cancer on a woman's life expectancy. The potential risks related to birth control pills seem to be small, however a yearly breast examination by a health care professional is recommended for all women.

### ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.

## 3. Cervical cancer

Some studies have found an increase of cancer of the cervix in women who use hormonal contraceptives, although this finding may be related to factors other than the use of oral contraceptives. However, there is insufficient evidence to rule out the possibility that oral contraceptives may cause such cancers.

## 4. Liver tumours

The short and long-term uses of birth control pills have also been linked with the growth of liver tumors. Such tumors are **extremely** rare.

Contact your doctor immediately if you experience severe pain or a lump in the abdomen.

## 5. Gallbladder disease

Users of birth control pills have a greater risk of developing gallbladder disease requiring surgery within the first year of use. The risk may double after four or five years of use.

## 6. Use in pregnancy

Birth control pills should not be taken by pregnant women. There is no evidence, however, that the birth control pill can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

## 7. Use after pregnancy, miscarriage or an abortion

Your doctor will advise you of the appropriate time to start the use of Indayo after childbirth, miscarriage, or therapeutic abortion.

## 8. Pregnancy after stopping Indayo

You will have a menstrual period when you stop using Indayo. You should delay pregnancy until another menstrual period occurs within four to six weeks. In this way, the pregnancy can be more accurately dated. Contact your doctor for recommendations on alternate methods of contraception during this time.

## 9. Use while breast feeding

If you are breast-feeding, consult your doctor before starting the birth control pill. The hormones in birth control pills are known to appear in breast milk. These hormones may decrease the flow of breast milk. Adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. You should use another method of contraception and only consider starting the birth control pill once you have weaned your child completely.

### INTERACTIONS WITH THIS MEDICATION

Certain drugs may interact with birth-control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Please inform your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also tell any other doctor or dentist who prescribes another drug (or the dispensing pharmacist) that you use Indayo. They can tell you if you need to use an additional method of contraception and if so, for how long.

#### Drugs that may interact with Indayo include:

- drugs used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates,

carbamazepine, lamotrigine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampin, rifabutin) and HIV infections (e.g. ritonavir)

- antibiotics (e.g. penicillins, tetracyclines) for infectious diseases; you may be at higher risk of a specific type of liver dysfunction if you take troleandomycin and oral contraceptives at the same time.
- Cyclosporine
- antifungals (griseofulvin)
- the herbal remedy St. John's Wort (primarily used for the treatment of depressive moods)
- cholesterol-lowering drugs (e.g. clofibrate)
- antihypertensive drugs (for high blood pressure)
- antidiabetic drugs and insulin (for diabetes)
- prednisone
- sedatives and hypnotics (e.g. benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate)
- pain medication (meperidine)
- antidepressants (e.g. clomipramine)
- some nutritional supplements (e.g. Vit. B12, folic acid)
- antacids (use 2 hours before or after taking Indayo.)
- hepatitis C drug combinations containing, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir.

The pill may also interfere with the working of other drugs.

*This is not a complete list of possible drug interactions with Indayo. Talk to your doctor for more information about drug interactions.*

#### PROPER USE OF THIS MEDICATION

1. **BE SURE TO READ THESE DIRECTIONS:**
  - Before you start taking your pills.
  - Anytime you are not sure what to do.
2. **THE RIGHT WAY TO TAKE INDAYO IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.**  
If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.

3. **MANY WOMEN MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST FEW WEEKS OF TAKING PILLS.**  
If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your healthcare professional.
4. **MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING DURING THE FIRST FEW MONTHS OF TAKING INDAYO.**  
**Do not stop taking your pills even if you are having irregular bleeding.** If the bleeding lasts for more than a few days, talk to your healthcare professional.
5. **MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING,** even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.
6. **IF YOU HAVE VOMITING OR DIARRHEA, or IF YOU TAKE SOME MEDICINES,** including some antibiotics and the herbal supplement St. John's Wort, Indayo may not work as well. Use a back-up method (such as condoms or spermicide) until you check with your healthcare professional.
7. **IF YOU HAVE TROUBLE REMEMBERING TO TAKE INDAYO** talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
8. **IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET,** call your healthcare professional.

#### BEFORE YOU START TAKING INDAYO

1. **DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL.** It is important to take it at about the same time every day.

**LOOK AT YOUR EXTENDED-CYCLE TABLET BLISTER PACK.** Your Tablet Blister Pack consists of 3 blister cards that hold 91 individually sealed pills (a 13-week or 91-day cycle). The 91 pills consist of 84 pink pills (active pills with hormones) and 7 white pills (inactive pills without hormone). Blisters 1 and 2 each contain 28 pink pills (4 rows of 7 pills).

Blister 3 contains 35 pills consisting of 28 pink pills (4 rows of 7 pills) and 7 white pills (1 row of 7 pills).

**ALSO FIND:**

- Where on the first tray in the pack to start taking pills (upper left corner at the start arrow) and
- In what order to take the pills (follow the weeks and arrow).

2. **BE SURE YOU HAVE READY AT ALL TIMES ANOTHER KIND OF BIRTH CONTROL** (such as condoms or spermicide), to use as a back-up in case you miss pills.

**WHEN TO START INDAYO**

1. Take the first “active” pink pill on the *Sunday after your period starts*, even if you are still bleeding. If your period begins on Sunday, start the first pink pill that same day.
2. *Use another method of birth control (such as condom or spermicide)* as a back-up method if you have sex anytime from the Sunday you start your first pink pill until the next Sunday (first 7 days).

**HOW TO TAKE INDAYO**

**1. Take one pill at the same time every day until you have taken the last pill in the tablet blister pack. Do not skip pills even if you are spotting or bleeding** or feel sick to your stomach (nausea). Do not skip pills even if you do not have sex very often.

**2. WHEN YOU FINISH A TABLET BLISTER PACK.**

After taking the last white pill, start taking the first pink pill from a new Extended-Cycle Tablet Blister Pack **the very next day** regardless of when your period started. This should be on a Sunday.

**3. If you miss your period when you are taking the white pills, call your healthcare provider because you may be pregnant.**

**Usual dose:**

One pink tablet should be taken daily for 84 consecutive days, followed by 7 days of white tablets.

**Overdose:**

If you think you, or a person you are caring for, have taken too much Indayo, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Symptoms of overdose may include nausea, vomiting or vaginal bleeding. Available information from cases of accidental ingestion of oral contraceptives by children indicates no serious effects. In case of an overdose, contact your healthcare professional or pharmacist.

**Missed Dose:**

If you **MISS one** pink “active” pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
2. You do not need to use a back-up birth-control method if you have sex.

If you **MISS two** pink “active” pills in a row:

1. Take 2 pills on the day you remember and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You **COULD BECOME PREGNANT** if you have sex in the *7 days* after you restart your pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back-up on the 7 days after you restart your pills.

If you **MISS 3 OR MORE** pink “active” pills in a row:

1. Do not remove the missed pills from the pack as they will not be taken. Keep taking 1 pill every day as indicated on the pack until you have completed all of the pills in the pack. For example: if you resume taking the pill on Thursday, take the pill under “Thursday” and do not take the previous missed pills. You may experience bleeding during the week following the missed pills.
2. You **COULD BECOME PREGNANT** if you have sex during the days of missed pills or during the first 7 days after you restart your pills.
3. You **must** use a non-hormonal birth control method (such as condoms or spermicide) as a back-up when you miss pills and for the first 7 days after you restart your pills. **If you miss your period when you are taking the white pills, call your healthcare professional because you may be pregnant.**

If you **MISS ANY** of the 7 white inactive pills.

1. Throw away the missed pills.
2. Keep taking the scheduled pills until the pack is finished.
3. You do not need a back-up method of birth control.

**FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED**

1. Use a **BACK-UP METHOD** anytime you have sex.
2. **KEEP TAKING ONE PILL EACH DAY** until you can consult your healthcare professional.

**IF YOU FORGET MORE THAN ONE PILL TWO MONTHS IN A ROW, TALK TO YOUR DOCTOR OR CLINIC** about ways to make pill-taking easier or about using another method of birth control.

**Non-contraceptive Benefits of Birth Control Pills**

Several health advantages have been linked to the use of birth control pills:

- Combination estrogen and progestin birth control pills reduce the incidence of cancer of the uterus and ovaries.
- Birth control pills reduce the likelihood of developing benign (non-cancerous) breast disease and ovarian cysts.
- Users of birth control pills lose less menstrual blood and have more regular cycles. The risk of developing iron-deficiency anemia is thus reduced.
- There may be a decrease in painful menstruation and in premenstrual syndrome (PMS).
- Acne, excessive hair growth and male-hormone related disorders also may be improved.
- Ectopic (tubal) pregnancy may occur less frequently.
- Acute pelvic inflammatory disease may occur less frequently.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The following side effects have been observed in studies of women taking Levonorgestrel and Ethinyl Estradiol Tablets.

Most side effects when using the birth control pill are not serious. The most common side effects are nausea, vomiting, bleeding or spotting between menstrual periods, weight gain, breast tenderness and difficulty wearing contact lens. Some of these side effects, especially nausea and vomiting may subside within the first 3 months of use.

Other side effects can occur such as fluid retention, darkening of the skin (particularly on the face),

headache, nervousness, depression, dizziness, loss of scalp hair, vaginal infections and allergic reactions. If any of these side effects occur, consult your healthcare professional.

Two subjects had pulmonary embolism and one subject had myocardial infarction while on Levonorgestrel and Ethinyl Estradiol Tablets in clinical studies.

You will have more bleeding or spotting between your menstrual periods than if you were taking an oral contraceptive with a 28-day treatment cycle. During the first Levonorgestrel and Ethinyl Estradiol Tablets treatment cycle, about 1 in 3 women may have 20 or more days of unplanned bleeding or spotting (bleeding when you are taking pink pills)

Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding which is a flow much like a regular period. Irregular bleeding occurs most often during the first few 91-day cycles of Levonorgestrel and Ethinyl Estradiol Tablets use, tends to decrease during later cycles, but may also occur after you have been taking Levonorgestrel and Ethinyl Estradiol Tablets for some time. Such bleeding usually does not indicate any serious problems. **It is important to continue taking your pills on schedule even if you are having irregular bleeding.** If the bleeding lasts for more than 7 consecutive days, talk to your healthcare professional.

Unscheduled bleeding and/or spotting as a reason for discontinuation for women using Levonorgestrel and Ethinyl Estradiol Tablets was reported more often during the first seven months of treatment as opposed to the last five months of treatment. The pattern of unscheduled bleeding and/or spotting continued to decrease as women continued treatment.

The following additional symptoms have been reported in women taking hormonal contraceptives in general:

- difficulty wearing contact lenses
- vaginal irritation or infections
- urinary tract infections or inflammation
- upper respiratory tract infections (colds, bronchitis, runny or stuffy nose, sore throat, etc.)
- severe headaches
- insomnia
- amenorrhea (lack of a period or breakthrough bleeding)
- flu-like symptoms

- allergy, fatigue, fever
- diarrhea, flatulence

In the post-market period, there have been cases of myocardial infarction, stroke, deep vein thrombosis and pulmonary embolism reported with the use of Levonorgestrel and Ethinyl Estradiol Tablets. These adverse events have been reported and their relationship to Levonorgestrel and Ethinyl Estradiol Tablets drug usage is not known.

Jaundice or yellowing of the skin or eyeballs accompanied frequently by fever, fatigue, loss of appetite, dark-coloured urine, or light-coloured bowel movements			√
High blood pressure			√
Unusual swelling of extremities		√	

**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 get immediate help
	Only if severe	In all cases	
<b>Uncommon</b>			
Sharp chest pain, coughing of blood, sudden shortness of breath			√
Pain in the calf			√
Crushing chest pain or heaviness in the chest			√
Sudden, severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg			√
Sudden partial or complete loss of vision			√
Breast lumps	√		
Severe pain or tenderness in the stomach area	√		
Difficulty sleeping, weakness, lack of energy, fatigue or change in mood			√

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

**HOW TO STORE IT**

Store at room temperature (15°C to 30°C).

**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**

- 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/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website <https://www.mylan.ca>, or by calling 1-844-596-9526.



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