

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**INDAYO**®

Levonorgestrel and Ethinyl Estradiol Tablets, USP

Read this carefully before you start taking **Indayo** 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 **Indayo**.

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 particularly in women over 35 years of age. The risk also increases with the number of cigarettes smoked. For this reason, women who smoke and are over 35 years of age should not use Indayo.

Birth control pills DO NOT PROTECT against Sexually Transmitted Infections (STIs), including HIV/AIDS.

For protection against STIs, it is advisable to use latex or polyurethane condoms AND take your birth control pills.

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). This higher exposure may increase the risk of developing blood clots.

What is Indayo used for?

Indayo is used for the prevention of pregnancy in women (18 years of age and older). Indayo should be used in women who have had their first menstrual period (menarche).

How does Indayo work?

Indayo is a birth control pill. It is considered to be a combination oral contraceptive. This is because it contains two female sex hormones, levonorgestrel and ethinyl estradiol. It has been shown to be effective in preventing pregnancy when taken as prescribed by your healthcare professional.

Combination hormonal contraceptives like Indayo work in two ways:

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

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 if Indayo is not used correctly.

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

There are differences in these pregnancy rates. This is because not all people use birth control as carefully or as regularly as they should. This does not apply to subdermal implants or IUDs since these are implanted under the skin or in the uterus. If you are careful and use your birth control regularly, pregnancy rates should be lower. Some types of birth control will require more effort than taking a single pill every day.

What are the ingredients in Indayo?

Medicinal ingredients: Levonorgestrel and ethinyl estradiol

Each pink active tablet contains the following inactive 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 white inert tablet contains the following inactive ingredients: lactose monohydrate, magnesium stearate and polacrillin potassium.

Indayo comes in the following dosage forms:

Pink tablets containing 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol.

White tablets containing no medicinal ingredients.

Do not use Indayo if:

- you have or have a history of blood clots in the legs or somewhere else in your body
- you have or have a history of a stroke, heart attack, or coronary artery disease (including angina pectoris), or a condition that may be a first sign of a stroke (such as a ministroke or small reversible stroke)
- you have a disease of the heart valves with complications
- you have the following risk factors for blood clots:
 - severe high blood pressure
 - diabetes with complications
 - known abnormalities of the blood clotting system such as:
 - Factor V Leiden mutation
 - activated protein C (APC) resistance
 - antithrombin-III-deficiency
 - protein C deficiency
 - protein S deficiency
 - hyperhomocysteinaemia
 - prothrombin mutation G20210A
 - antiphospholipid-antibodies
 - very high blood cholesterol or triglyceride levels
- you have or will have a major surgery (including to the legs, pelvis or nervous system)
- you cannot stand or move for long periods of time, including prolonged bed rest
- smoke heavily (more than 15 cigarettes per day) and are over age 35
- you have or have a history of migraine headaches with focal aura (flashes or light, blind spots and other vision changes)
- you have liver disease
- you have or have had liver tumours (cancerous or non-cancerous)
- you have or have had jaundice. This is where the skin or whites of the eyes turn yellow. This may have been related to other medicines you were taking or may have happened during pregnancy.
- you have or think you have cancer of the breast or uterus (womb) or other estrogen-dependent cancer

- you have unusual vaginal bleeding without a known reason
- you have loss of vision due to blood vessel disease of the eye
- you are pregnant or think you might be pregnant
- you have or have a history of pancreatitis (inflammation of the pancreas) associated with high levels of fatty substances in your blood
- you are allergic to ethinyl estradiol, levonorgestrel or to any of the non-medicinal ingredients in Indayo (see **What are the ingredients in Indayo?**)
- you are using antiviral medications to treat Hepatitis C Virus (HCV) which contain the combination of glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir

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

- smoke
- have a history of breast disease (such as breast lumps) or a family history of breast cancer
- have high blood pressure
- have high cholesterol
- have or have a family history of diabetes
- have or have a history of heart, liver or kidney problems
- have a history of seizures/epilepsy
- have a history of depression
- have cholestasis. This is a condition where bile flow from the liver is decreased.
- wear contact lenses
- have uterine fibroids (benign tumours of the uterus)
- are breast feeding
- have systemic lupus erythematosus. This is a disease of the immune system that affects the joints, skin, kidneys, blood cells, brain, heart and lungs.
- have inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have hemolytic uremic syndrome. This is when there is an abnormal breakdown of blood cells, which clog the kidneys.
- have sickle cell disease. This is a disease that affects haemoglobin, a molecule in red blood cells that delivers oxygen throughout the body.
- 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.
- have a history of a skin condition called chloasma (hyperpigmentation)
- are overweight
- have a family history of blood clot disorders, heart attacks or strokes

Other warnings you should know about:

Blood Clot in Legs, Lungs, Heart, Eyes or Brain

Women who use birth control that contains hormones are more likely to develop blood clots. Blood clots are the most common serious side effects of birth control pills. The risk for clots is highest during the first year a woman uses a hormonal birth control. The risk is also high if a woman restarts the same or new hormonal birth control. Clots can occur in many areas of the body and can lead to blindness or impaired vision as well as damage to or loss of a limb and death.

While you are taking Indayo, if you have any of the below symptoms, talk to your healthcare professional right away. These are signs of blood clots:

- sharp pain in your chest
- coughing up blood
- sudden shortness of breath
- crushing chest pain or chest heaviness
- irregular heartbeat
- sudden severe or worsening headache
- feeling full
- vomiting
- dizziness, trouble walking
- fainting, seizures
- anxiety, confusion
- changes in vision
- changes in speech
- pain and / or swelling in your calf
- weakness or numbness in your face, arm or leg
- sudden pain, swelling and slight blue or red discoloration of an arm or leg
- discomfort radiating to your back, jaw, throat or stomach

Blood clots can develop whether or not you are using hormones for birth control. They can also happen if you are pregnant. The risk is higher in users of combined hormonal contraceptives (CHCs), including Indayo than in nonusers, but it is not as high as the risk during pregnancy. You should talk to your healthcare professional about the available options.

Cancer

Using birth control pills may increase the risk of certain cancers including cancer of the breast, cervix and liver.

Breast cancer: The risk of breast cancer in women increases as you get older. It also increases if there is family history of breast cancer, meaning if your mother or sister have or had breast cancer. Other factors that increase your risk for breast cancer are being obese, never having children, or having your first full-term pregnancy at a late age.

If you have breast cancer now, or had it in the past, do not use birth control pills. The hormones in these pills can affect some cancers.

Some women who use birth control pills may have a higher risk of developing breast cancer before menopause. These women may have used birth control pills for a long time (more than eight years), or may have started using birth control pills at an early age.

In a few women, using of birth control pills can speed up the growth of a breast cancer that has not yet been found. Finding breast cancer early can reduce the effect of the cancer on a woman's life expectancy. The risks for breast cancer related to using birth control pills seem to be small. You should, however, have a healthcare professional check your breasts at least once per year.

While you are taking Indayo, check your breasts often. See your healthcare professional if you notice any changes, such as:

- dimpling or sinking of the skin
- changes in the nipple
- any lumps you can see or feel

Cervical cancer: Human Papilloma Virus (HPV) is an important risk factor for cervical cancer. However, it is possible that women who use birth control pills may have a higher chance of getting cervical cancer.

Liver cancer: Liver cancer (hepatocellular carcinoma) and liver tumors may be linked to oral birth control pills. The risk for liver cancer increases the longer these pills are used. However, liver tumors are extremely rare. If you feel severe abdominal pain or find a lump in your abdomen, talk to your healthcare professional right away. Do not use Indayo if you have a history of liver tumors (cancerous or noncancerous).

Gallbladder disease

The risk for gallbladder disease that needs surgery is higher in women using birth control pills. The risk is highest in the first year of use and increases the longer these pills are used.

Pregnancy, Breastfeeding, Miscarriage and Abortions

Use in pregnancy: Birth control pills should not be taken by pregnant women. Stop taking Indayo if you get pregnant. You should talk to your healthcare professional about risks to your unborn child from any medication taken during pregnancy.

Use after pregnancy, miscarriage or an abortion: You will be at an increased risk for blood clots. Your healthcare professional will tell you when to start using Indayo after childbirth, miscarriage or an abortion.

Pregnancy after stopping Indayo: You will have a menstrual period when you stop using Indayo. Wait until after your next period before getting pregnant. This will help to better date the pregnancy. Talk to your healthcare professional about other forms of birth control you can use during this time.

Breast-feeding: If you are breast-feeding, talk to your healthcare professional before starting the birth control pill. Other types of birth control, instead of a birth control pill, are recommended until your baby has stopped breast-feeding. The hormones in the pill may lower

the amount and quality of your breast milk. This may not happen, however, if you wait until after breast-feeding is established.

Skin conditions

Chloasma may develop while you are using Indayo. This appears as yellowish-brown patches on the skin, particularly of the face. It is more likely to happen if you have previously had chloasma gravidarum. This is when these patches appear on the skin of the face during pregnancy. This is commonly known as “the mask of pregnancy”. If you have or had chloasma, avoid too much exposure to the sun while using Indayo.

Surgery

Tell your healthcare professional if you are scheduled for major surgery. You may need to stop using Indayo four weeks before surgery. You may need to wait a time period after surgery or bed rest before restarting Indayo. Talk to your healthcare professional about other forms of birth control you can use during this time.

Vaginal bleeding

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 you may have 20 or more days of unplanned bleeding or spotting (bleeding when you are taking the pink pills). This bleeding or spotting tends to decrease during late cycles. Do not stop taking Indayo because of the bleeding. If the spotting continues for more than a few days or if the bleeding is heavy, talk to your healthcare professional.

While you are taking Indayo, you should have your period when you are taking the white pills. If you were not taking Indayo as directed by your healthcare professional or miss your period, you should have a pregnancy test. This will rule out if the missed period is because you are pregnant.

Check-Ups and Tests

Before starting Indayo, you will need to have examinations and tests. Your healthcare professional will conduct a physical exam. They will examine your breasts, liver, arms and legs. They will conduct a pelvic exam which includes a PAP smear. Your healthcare professional will also ask you some questions about your personal health history and that of your close relatives. They will also measure your blood pressure and do blood tests.

While you are taking Indayo, you will need regular check-ups with your healthcare professional to identify side effects associated with its use. Your first check-up should be about three months after starting Indayo. Afterward, you will see your healthcare professional at least once a year.

If you are scheduled for any laboratory tests, be sure to tell your healthcare professional that you are taking Indayo. This is because birth control pills can affect some blood tests.

If you see a different healthcare professional be sure to tell them that you are taking Indayo.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Certain drugs may interact with birth control pills (including Indayo) and prevent them from working properly. This can make them less effective in preventing pregnancy or cause unexpected bleeding (spotting or breakthrough bleeding). Birth control pills may also interfere with how other drugs work. If you are taking medicines or herbal products that might make Indayo less effective, a barrier method of birth control should also be used.

The following may interact with Indayo:

- drugs used for the treatment of epilepsy including primidone, phenytoin, barbiturates, carbamazepine, lamotrigine, ethosuximide and phenobarbital
- drugs used for the treatment of HIV infections or AIDS
- drugs used for the treatment of tuberculosis including rifampin
- drugs used to treat bacterial infections including penicillins, tetracyclines, troleandomycin, cotrimoxazole, ampicillin, chloramphenicol, metronidazole, neomycin, nitrofurantoin and sulfonamides
- drugs used to prevent organ rejection including cyclosporine
- drugs used to treat fungal infection including griseofulvin
- St. John's Wort, an herbal product used to treat depression and other conditions
- drugs used to lower cholesterol including clofibrate
- drugs used to treat high blood pressure including guanethidine, methyldopa, reserpine and beta blockers
- antidiabetic drugs and insulin (for diabetes)
- drugs used to help you relax or sleep including benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate, chlordiazepoxide, lorazepam, oxazepam, and diazepam
- drugs used to treat fever, pain or inflammation including meperidine, prednisone, phenylbutazone, acetaminophen, antipyrine and ASA
- drugs used to treat depression including clomipramine
- some nutritional supplements including Vitamin E, Vitamin B12, and folic acid
- antacids
- hepatitis C drug combinations containing, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir.
- drugs used to treat lung problems including theophylline
- drugs used to treat allergies including antihistamines
- drugs used to treat migraine headaches
- aminocaproic acid, used to help treat bleeding
- alpha-II adrenoreceptor agents including clonidine
- drugs used to prevent blood clots
- drugs used to treat mental health problems including phenothiazines

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

Antacids may affect how Indayo is absorbed in your body. If you need to use antacids, like TUMS, take them 2 hours before or 2 hours after taking Indayo.

The effects of caffeine and alcohol may be increased. This is because birth control pills affect how these are metabolized.

Do not use Indayo if you have Hepatitis C and are being treated with glecaprevir / pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir. Using these drugs at the same time as Indayo can cause problems with your liver, such as an increase in the ALT liver enzyme. You can usually start Indayo about 2 weeks after finishing treatment with these combination drugs used for Hepatitis C, but talk to your healthcare professional before taking Indayo.

How to take Indayo:

1. BE SURE TO READ THESE DIRECTIONS:
 - Before you start taking your pills.
 - Anytime you are not sure what to do.
2. Decide with your healthcare professional what time of day is best for you to start taking your first pill. It is important that you take the pill at about the same time each day. Pick a time of day that will be easy to remember.
3. Look at your Extended-Cycle Tablet Dispenser. The Indayo Extended-Cycle Tablet Dispenser has 3 trays with cards that hold 91 individual sealed pills. The 91 pills consist of 84 pink pills that contain hormones and 7 white pills that contain no hormones. Tray 1 and Tray 2 each contain 28 pink pills. Tray 3 contains 28 pink pills and 7 white pills (35 pills in total). Check the pill pack for:
 - where to start taking pills
 - in what order to take the pills
4. Your healthcare professional will tell you to start taking the pills on the first Sunday after your period begins. If your period starts on Sunday, start the same day.
5. Take 1 pill at approximately the same time every day for 91 days. Begin a new Extended-Cycle Tablet Dispenser the next day, **NOT MISSING ANY DAYS**. Your period should occur during the last seven days of using that pill pack, while you are taking the white pills. You should expect to have 4 menstrual periods per year.
6. Taking Indayo:
 - Take Indayo exactly as directed by your healthcare professional.
 - Take your pill at approximately the same time every day. Try to associate taking your pill with a regular activity like eating a meal or going to bed. This will help you remember to take it.
 - Start taking Indayo the first Sunday after your period starts. If your period starts on Sunday, start that same day.
 - Take Indayo according to this schedule:
 - Take 1 pink pill each day for 84 days in a row. You should always begin a pack by starting with the pink colored pills. You should always take the pink colored pills first.
 - Then, take 1 white pill for 7 days in a row.

- Start the next pack on the day after your last white pill. Do not wait any days between packs.
- Be sure to take all the pills in each pack.
- Do not skip any of the pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach.
- Do not skip pills even if you do not have sex very often.
- Use another barrier method of birth control (such as a condom) for the first 7 days of your first cycle of Indayo.

Indayo may not work as well as it should to prevent pregnancy if you:

- miss pills
- don't take your pills as directed by your healthcare professional
- have gastrointestinal problems such as vomiting or diarrhea
- are taking certain medicines

If this happens, you should use another method of birth control, like condoms (barrier method). Do this while taking Indayo and until you start a new pack of Indayo. Talk to your healthcare professional if you are not sure.

You might notice bleeding or spotting during the first few months of taking Indayo. Do not stop taking your pills even if you have irregular bleeding. If the bleeding lasts for more than a few days, talk to your healthcare professional.

If you do not get your period when you are taking the white pills, talk to your healthcare professional. You might be pregnant.

Usual dose:

Take 1 pink pill a day. When all 84 pink pills are done, take 1 white pill a day for 7 days.

Overdose:

Symptoms of overdose may include:

- nausea
- vomiting
- breast tenderness
- dizziness
- abdominal pain
- drowsiness, fatigue
- vaginal bleeding.

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.

Missed Dose:

If you miss pink coloured pills, you could get pregnant. The more pink pills you miss, the more likely you are to get pregnant. If you miss one or more pink coloured pills and do not have a period that month, you may be pregnant. If this happens, talk to your healthcare professional.

Missing pills can cause spotting or light bleeding, even when you make up these missed pills.

If you forget more than one pill two months in a row, talk to your healthcare professional about ways to make pill-taking easier or about using another method of birth control.

Always be sure to have on hand a back-up method of birth control. These are types that do not include hormones, like latex or polyurethane condoms and spermicidal foam or gel. You will need back-up birth control if you miss pills and in some other situations. Always talk to your healthcare professional if you are not sure whether you need to use back-up birth control.

If you **MISS 1** pink pill:

1. Take the missed pill as soon as possible and take the next pill at the usual time. This means you take 2 pills in 1 day. On the days you take 2 pills to make up for the missed pill, you could feel a little sick to your stomach.
2. Keep taking 1 pill a day until the pack is finished.

If you **MISS 2** pink 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. Use a back-up barrier method of birth control (such as condoms or spermicide) if you have sex in the 7 days after you miss the pills.

If you **MISS 3 OR MORE** pink 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. Use a back-up barrier method of birth control (such as condoms or spermicide) if you have sex in the 7 days after you miss the pills. **If you miss your period when you are taking the white pills, you might be pregnant. Talk to your healthcare professional right away.**

If you **MISS ANY** of the 7 white pills:

1. Safely dispose of the pills you missed.
2. Keep taking 1 pill each day until the pack is empty.
3. You do not need to use a back-up barrier method of birth control.

If you are not sure about the number or the colour of pills missed:

Talk to your healthcare professional right away.

What are possible side effects from using Indayo?

These are not all the possible side effects you may have when taking Indayo. If you experience any side effects not listed here, tell your healthcare professional.

The following side effects may occur:

- bleeding or spotting between periods
- nausea, vomiting, feeling sick to the stomach
- abdominal cramps, bloating
- changes in weight, changes in appetite
- breast tenderness
- difficulty wearing contact lenses
- darkening of the skin (particularly on the face)
- upper respiratory tract infections (colds, bronchitis, runny or stuffy nose, sore throat, etc.)
- flu-like symptoms (fever, cough, sore throat, runny nose, feeling tired)
- urinary tract infection or inflammation
- vaginal infection
- diarrhea
- changes in libido
- abdominal cramps
- bloating
- constipation
- muscle cramps, muscle spasms
- neck pain, joint pain, back pain
- acne, aggravated acne
- fluid retention
- headache
- nervousness
- dizziness
- insomnia
- loss of scalp hair

Some of these side effects, especially bleeding or spotting, nausea, vomiting, and feeling sick to the stomach may subside within the first 3 months of use. If the problem doesn't go away, talk to your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Blood clot in the eye: sudden partial or complete loss of vision			x
Breast changes (breast lumps/breast cancer): pain and tenderness, lumps, nipple discharge		x	
Deep vein thrombosis (blood clot in the leg): swelling of one leg or one foot, pain or tenderness in the leg, difficulty standing or walking, feeling of warmth in the leg, red or discoloured skin on the leg, sudden pain, swelling and slight blue discolouration of an extremity			x
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse.			x
Edema: unusual swelling of extremities		x	
Gallbladder disease: nausea, vomiting, pain on the upper right side of the abdomen,		x	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
especially after meals, loss of appetite, fever			
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations			x
Jaundice (build up of bilirubin in the blood): yellowing of the skin and eyes, dark urine, light coloured stool, itching all over your body			x
Liver tumor: abdominal pain, nausea or vomiting or lump in the abdomen		x	
Myocardial infarction (heart attack): pressure or squeezing pain in the chest, jaw, left arm, between the shoulder blades or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			x
Pulmonary embolism (blood clot in the lung): sharp chest pain, coughing of blood, sudden shortness of breath			x
Stroke: sudden, severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg			x

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Unexpected vaginal bleeding		x	
UNKNOWN FREQUENCY			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			x

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

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.

Storage:

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

Keep out of reach and sight of children and pets.

If you want more information about Indayo:

- 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: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug->

[products/drug-product-database.html](https://www.mylan.ca/products/drug-product-database.html); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

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