CONSUMER INFORMATION
PrESTALIS® 140/50
(estradiol-17β + Norethindrone Acetate transdermal system)

PrESTALIS® 250/50
(estradiol-17β + Norethindrone Acetate transdermal system)

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

ABOUT THIS MEDICATION

What the medication is used for:

- ESTALIS ® should only be used if you have a uterus (it has not been surgically removed) to reduce moderate or severe menopausal symptoms
- To treat vulval and vaginal atrophy (itching, burning or dryness in or around the vagina, difficulty or burning on urination)

ESTALIS® should be used only under the supervision of a doctor, with regular follow-up at least once a year to identify side effects associated with its use. Your first follow-up visit should be within 3 to 6 months of starting treatment. Your visit may include a blood pressure check, a breast exam, a Pap smear and pelvic exam. You should have a mammogram before starting treatment and at regular intervals as recommended by your doctor. Your doctor may recommend some blood tests.

You should carefully discuss the risks and benefits of hormone replacement therapy (HRT) with your doctor. You should regularly talk with your doctor about whether you still need treatment with HRT.

What it does:

Treatment with ESTALIS® offers relief from menopausal symptoms for women with uteri. With ESTALIS® used in a continuous regimen, you receive estradiol and norethindrone acetate (NETA), a progestin, throughout the entire 28-day cycle. The progestin provides important protection for your uterus (See **Uses Of Progestins**).

Uses Of Estrogens

The main estrogen produced by your ovaries prior to menopause is estradiol, and this is the same estrogen that is in ESTALIS® When applied to the skin, the ESTALIS® patches continually release small, controlled quantities of estradiol, which pass through your skin and into your bloodstream. The amount of estrogen prescribed depends on your body's needs.
By providing estradiol, ESTALIS® offer relief from menopausal symptoms.

Your body normally makes estrogens and progestins (female hormones) mainly in the ovaries. Between ages 45 and 55, the ovaries gradually stop making estrogens. This leads to a decrease in body estrogen levels and a natural menopause (the end of monthly menstrual periods). If both ovaries are removed during an operation before natural menopause takes place, the sudden decrease in estrogen levels causes "surgical menopause".

Menopause is not a disease - it is a natural life event and different women experience menopause and its symptoms differently. Not all women suffer obvious symptoms of estrogen deficiency. When the estrogen levels begin decreasing, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden intense episodes of heat and sweating ("hot flashes" or " hot flushes"). Using estrogen drugs can help the body adjust to lower estrogen levels and reduce these symptoms.

Uses Of Progestins

Progestins used in hormone replacement therapy have similar effects to the female sex hormone progesterone. During the child bearing years, progesterone is responsible for regulation of the menstrual cycle. The estradiol delivered by ESTALIS® not only relieves your menopausal symptoms, but, like estrogens produced by your body, may also stimulate growth of the inner lining of the uterus, the endometrium. In menopausal and postmenopausal women with intact uteri, stimulation of growth of the endometrium may result in irregular bleeding. In some cases this may progress into a disorder of the uterus known as endometrial hyperplasia (overgrowth of the lining of the uterus), which increases the risk of endometrial cancer (cancer of the lining of the uterus). The development of estrogen-mediated disorders of the uterus can be reduced if a progestin, such as norethindrone acetate, is given regularly for a certain number of days with your estrogen replacement therapy. For women receiving ESTALIS® in a continuous combined regimen, it is expected that uterine bleeding will stop

within a period of a few months and such treatment should also be protective of endometrial hyperplasia.

When it should not be used

Certain medical conditions may be aggravated by estrogens and progestins, therefore these hormones should not be used at all under these conditions.

ESTALIS® should not be used under the following conditions:

- if you are pregnant or think you may be pregnant. Since pregnancy may be possible early in menopause while you are still having spontaneous periods, the use of non-hormonal birth control should be discussed with your physician at this time. If you take estrogen during pregnancy, there is a small risk of your unborn child having birth defects.
- if you are breast-feeding. Ask your doctor or pharmacist for advice.
- if you currently have or have ever had cancer of the breast, or uterus or endometrium (lining of the womb) or any other estrogen-dependent cancer
- If you have been diagnosed with endometrial hyperplasia (overgrowth of the lining of the uterus)
- if you have unexpected or unusual genital bleeding
- if you have active thrombophlebitis (inflamed varicose veins)
- if you currently have a problem with blood clots forming in your blood vessels or have ever had such a problem in the past. This may cause painful inflammation of the veins (thrombophlebitis) or blockage of a blood vessel in the legs (deep vein thrombosis), lungs (pulmonary embolism) or other organs
- if you have ever had coronary heart disease, a heart attack or stroke
- if you have serious liver disease
- if you have migraine
- if you have had partial or complete loss of vision due to blood vessel disease in the eye.
- if you have a disease of blood pigment called porphyria
- if you have had any unusual allergic reaction to estrogens or any other component of ESTALIS® (see **What the medicinal ingredient is and What the-nonmedicinal ingredients are**).

Talk to your doctor if you have any further questions or if you think that any of the above may apply to you.

What the medicinal ingredients are:

The active components of the system are estradiol (an estrogen hormone) USP and norethindrone acetate (NETA – a progesterone hormone) USP

What the nonmedicinal ingredients are:

a silicone and acrylic -based multipolymeric adhesive, povidone USP, oleic acid NF, and dipropylene glycol.

What dosage forms it comes in:

ESTALIS® packs contain 8 patches. ESTALIS® (NETA/17ß-estradiol) patches are available in two strengths : ESTALIS® 140/50 and ESTALIS® 250/50.

Serious Warnings and Precautions

The Women's Health Initiative (WHI) trial is a large clinical study that assessed the benefits and risks of oral combined *estrogen plus progestin* therapy and oral *estrogen-alone* therapy compared with placebo (a pill with no active ingredients) in postmenopausal women.

The WHI trial indicated an increased risk of myocardial infarction (heart attack), stroke, breast cancer, pulmonary emboli (blood clots in the lungs) and deep vein thrombosis (blood clots in the large veins) in postmenopausal women taking oral combined *estrogen plus progestin*.

The WHI trial indicated an increased risk of stroke and deep vein thrombosis in postmenopausal women with prior hysterectomy (surgical removal of the uterus) taking oral *estrogen-alone*.

Therefore, you should highly consider the following:

- There is an increased risk of developing invasive breast cancer, heart attack, stroke and blood clots in both lungs and large veins with the use of estrogen plus progestin therapy.
- There is an increased risk of stroke and blood clots in the large veins with the use of estrogen-alone therapy.
- Estrogens with or without progestins should not be used for the prevention of heart disease or stroke.
- Estrogens with or without progestins should be used at **the lowest effective dose** and for **the shortest period of time** possible. Regular medical follow-up is advised.

[Reworded and added to comply with GUIDANCE FOR INDUSTRY: Product Monographs of Non-Contraceptive Estrogen / Progestin-Containing Products]

WARNINGS AND PRECAUTIONS

- **Breast cancer**

The results of the WHI trial indicated an increased risk of breast cancer in post-menopausal women taking combined *estrogen plus progestin* compared to women taking placebo.

The results of the WHI trial indicated no difference in the risk of breast cancer in postmenopausal women with prior hysterectomy taking *estrogen-alone* compared to women taking placebo.

Estrogens with or without progestins should not be taken by women who have a personal history of breast cancer.
In addition, women with a family history of breast cancer or women with a history of breast lumps, breast biopsies or abnormal mammograms (breast x-rays) should consult with their doctor before starting hormone replacement therapy.

Women should have a mammogram before starting HRT and at regular intervals during treatment as recommended by their doctor.

Regular breast examinations by a doctor and regular breast self-examinations are recommended for all women. You should review technique for breast self-examination with your doctor.

- **Overgrowth of the lining of the uterus and cancer of the uterus**

The use of estrogen-alone therapy by post menopausal women who still have a uterus increases the risk of developing endometrial hyperplasia (overgrowth of the lining of the uterus), which increases the risk of endometrial cancer (cancer of the lining of the uterus).

The purpose of adding a progestin medication to estrogen therapy is to reduce the risk of endometrial hyperplasia.

You should discuss progestin therapy and risk factors for endometrial hyperplasia and endometrial carcinoma with your doctor. You should also report any unexpected or unusual vaginal bleeding to your doctor.

If you have had your uterus removed, you are not at risk of developing endometrial hyperplasia or endometrial carcinoma. Progestin therapy is therefore not generally required in women who have had a hysterectomy.

- **Ovarian cancer**

In some studies, the use of estrogen-alone and estrogen plus progestin therapies for 5 or more years has been associated with an increased risk of ovarian cancer.

- **Heart disease and Stroke**

The results of the WHI trial indicated an increased risk of stroke and coronary heart disease in post-menopausal women taking combined *estrogen plus progestin* compared to women taking placebo.

The results of the WHI trial indicated an increased risk of stroke, but no difference in the risk of coronary heart disease in post-menopausal women with prior hysterectomy taking *estrogen alone* compared to women taking placebo.

- **Abnormal Blood Clotting**

The results of the WHI trial indicated an increased risk of blood clots in the lungs and large veins in post menopausal women taking combined *estrogen plus progestin* compared to women taking placebo.

The results of the WHI trial indicated an increased risk of blood clots in the large veins, but no difference in the risk of blood clots in the lungs in post-menopausal women with prior hysterectomy taking *estrogen-alone* compared to women taking placebo.

The risk of blood clots increases with age, if you or a family member has had blood clots, if you smoke or if you are severely overweight. The risk of blood clots is also temporarily increased if you are immobilized for long periods of time and following major surgery. You should discuss risk factors for blood clots with your doctor since blood clots can be life-threatening or cause serious disability.

- **Gallbladder disease**

The use of estrogens by postmenopausal women has been associated with an increase risk of gallbladder disease requiring surgery.

- **Dementia**

The Women's Health Initiative Memory Study (WHIMS) was a substudy of the WHI trial and indicated an increased risk of dementia (loss of memory and intellectual function) in post-menopausal women age 65 and over taking oral combined *estrogen plus progestin* compared to women taking placebo.

The WHIMS indicated no difference in the risk of dementia in post-menopausal women age 65 and over with prior hysterectomy taking oral *estrogen-alone* compared to women taking placebo.

Before you use ESTALIS® talk to your doctor or pharmacist if you:

- have a history of severe allergic reaction or intolerance to any medications or other substances
- have been told that you have a condition called hereditary angioedema of if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract
- have a personal history of breast disease (including breast lumps) and/or breast biopsies, or a family history of breast cancer
- have experienced any unusual or undiagnosed vaginal bleeding
- have a history of uterine fibroids or endometriosis
- have a history of liver disease or liver tumours, jaundice (yellowing of the eyes and/or skin) or itching related to estrogen use or during pregnancy
- have a history of migraine headache
- have a history of high blood pressure
- have a personal or family history of blood clots, or a personal history of heart disease or stroke
- phlebitis (inflamed varicose veins)
- **If you have** had several miscarriages.
- have a history of kidney disease or asthma
- have a history of bone disease (this includes certain metabolic conditions or cancers that can affect blood levels of calcium and phosphorus)
- have been diagnosed with diabetes
- have been diagnosed with porphyria (a disease of blood pigment)
- have been diagnosed with lupus
- gall bladder disease
- depression
- have been diagnosed with hearing loss due to otosclerosis
- epilepsy (seizures) or other neurological disorders
- have a history of high cholesterol or high triglycerides
- are pregnant or may be pregnant
- are breastfeeding
- have had a hysterectomy (surgical removal of the uterus)
- smoke
- are undergoing surgery or need long bed rest.
- Have been told that you have hypothyroidism (a condition in which your thyroid gland fails to produce enough thyroid hormone) and you are treated with thyroid hormone replacement therapy

Ask your doctor and pharmacist to answer any questions you may have.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medications, including prescription medications, over-the-counter medications, vitamins or herbal products.

This particularly includes the following:

- Acetaminophen
- Aminoglutethimide with medroxyprogesterone acetate (MPA)
- anti-anxiety medicines (meprobamate, temazepam),
- cyclosporin
- anti-epileptic medicines (e.g. phenobarbital, phenytoin or carbamazepine),
- an anti-inflammatory medicine called phenylbutazone,
- antibiotics and other anti-infective medicines (e.g. ketoconazole, erythromycin, rifampicin, rifabutin, nevirapine, efavirenz, ritonavir and nelfinavir), and
- herbal medicines (e.g. St John's wort)
- morphine
- prednisone
- salicylic acid
- theophylline
- Vitamin C

These medicines may be affected by ESTALIS® or, conversely, they may affect how well ESTALIS works. Your doctor may need to adjust the dose of your treatment.

Tell your doctor that you are on treatment with ESTALIS® if you are going to have laboratory tests. Some laboratory tests, such as tests for glucose tolerance or thyroid function, may be affected by ESTALIS® therapy.

PROPER USE OF THIS MEDICATION

Usual dose:

ESTALIS®: ESTALIS® packs contain 8 patches. ESTALIS® (NETA/17ß-estradiol) patches are available in two strengths , called ESTALIS® 140/50 and ESTALIS® 250/50, each containing and releasing different amounts of estradiol and norethindrone acetate, as follows:

- ESTALIS® 140/50: 9 cm^2 patch, containing 0.620 mg estradiol and 2.70 mg NETA, and releasing around 50 µg estradiol and 140 µg NETA per day.
- ESTALIS® 250/50: 16 cm^2 patch, containing 0.512 mg estradiol and 4.80 mg NETA, and releasing around 50 µg estradiol and 250 µg NETA per day.

Your doctor will prescribe the patches in a continuous regimen.

Continuous Regimen
The ESTALIS® patch is worn continuously for the 4 weeks of the cycle (see Figure 1). The ESTALIS® patches are applied twice weekly on the same days of each week. Each patch should be worn continuously for 3-4 days.

Figure 1

Week 1	○	○	ESTALIS® patch for the 4 weeks of the cycle
Week 2	○	○	
Week 3	○	○	
Week 4	○	○	

The next treatment cycle is started immediately after removal of the last ESTALIS® patch. Irregular uterine bleeding may occur particularly in the first 6 months, but generally decreases with time.

It is important that you take your medication as your physician has prescribed. Do not discontinue or change your therapy without consulting your physician first.

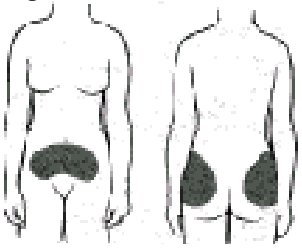
How And Where To Apply ESTALIS®
It is recommended that you change the site of application each time the patch is applied. In other words, each time you apply a patch, place it on a different area of your abdomen or buttocks than used before. The same area should not be used again for at least one week. However, each time you apply a patch you should always apply it to the same area of your body (i.e., if the patch is applied to the buttocks, move the patch from right side to left side, twice a week or more if there is any redness under the patch).

Apply whole patches.

1. Preparing The Skin
In order for the patch to stick, the skin should be clean, dry, cool and free of any powder moisturizer, lotions or oils. If you wish, you may use body lotion after the patch has been properly applied to the skin. The skin should not be irritated or broken, since this may alter the amount of hormone you get. Contact with water (bath, pool, or shower) should not affect the patch **(see Helpful Hints)**.

2. Where To Apply The ESTALIS® Patches
The patches may be applied to the buttocks or abdomen (see Figure 3). Change the site of application each time you put a patch on. A **one week period** should elapse before applying the patch to a previously used spot.

Figure 3

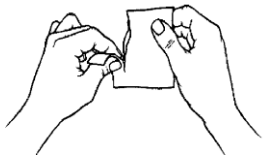


Avoid areas of the skin where clothing may rub the patch off or areas where the skin is very hairy or folded. Also avoid areas where the patch is likely to be exposed to the sun since this may affect how the patch works.

DO NOT APPLY THE PATCHES TO YOUR BREAST, since this may cause unwanted effects and discomfort.

3. Opening The Pouch
The patches contained in ESTALIS® are individually sealed in a protective pouch. **Tear** open this pouch at the indented notch and remove the patch (see Figure 4). Do not use scissors, as you may accidentally cut and destroy the patch.

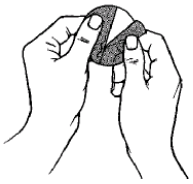
Figure 4



4. Removing The Liner
One side of the patch has the adhesive that sticks to your skin. The adhesive is covered by a protective liner that must be removed.

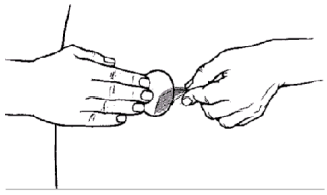
To separate the patch from the liner, hold the patch with the protective liner facing you. Peel off one side of the protective baking and discard it (see Figure 5). Try to avoid touching the sticky side of the patch with your fingers.

Figure 5



Using the other half of the baking as a handle, apply the sticky side of the system to a dry area of your abdomen or buttocks. Press the sticky side on the skin and smooth down.

Fold back the remaining side of the patch. Grasp the straight edge of the protective backing and pull it off the patch. (see Figure 6). Avoid touching the adhesive.
Figure 6



5. Applying The ESTALIS® patches
Apply the adhesive side to the spot you have chosen. Press it firmly in place with the palm of your hand for about 10 seconds, then run your finger around the edge, making sure there is good contact with the skin. Apply the patch soon after opening the pouch and removing the protective backing.

ESTALIS®should be worn continuously until it is time to replace it with a new patch. You may wish to experiment with different locations when applying a new patch, to find sites that are most comfortable for you, where clothing will not rub against the patch.

6. When And How To Remove The Patch
Continuous Regimen: The ESTALIS® patch should be changed twice weekly. Always change it on the same 2 days of the week. If you forget to change it at the scheduled time, there is no cause for alarm. Just change it as soon as possible and **continue** to follow your usual schedule.

After you remove the patch fold it in half with the adhesive sides inwards. **Throw it away, safely out of the reach of children or pets**.

Any adhesive left on your skin should rub off easily. You can also use mineral oil, baby oil or rubbing alcohol to remove adhesive from the skin. Apply a new ESTALIS® patch on a different spot of clean, dry skin.

The drug in your patch is contained in the adhesive and not in a special reservoir.

Helpful Hints

What to do if the patch falls off

Should a patch fall off in a very hot bath or shower, shake the water off the patch. Dry your skin completely and reapply the patch as soon as possible (to a different area of skin) and continue your regular schedule. Make sure you choose a clean, dry, lotion-free area of skin. If it still does not stick completely to your skin, then use a **new** patch. No matter what day this happens, go back to changing this patch on the same days as the initial schedule.

If hot baths, saunas or whirlpools are something you enjoy and you find that the patch is falling off, you may consider removing the patch **temporarily** while you are in the water. If you do remove the patch temporarily, the adhesive side of the patch should be placed on the protective liner that was removed when originally applying the patch. Wax paper may be used as an alternate to the liner. This prevents the contents of the patch from emptying by evaporation while you are not wearing it.

In addition to exposure to very hot water, there are some other causes for the patch failing to stick. If you are having patches fall off regularly, this could be happening as a result of:

- using any type of bath oil
- using soaps with a high cream content

- using skin moisturizers before applying the patch

Patch adhesion may be improved if you avoid using these products, and by cleansing the site of application with rubbing alcohol before you apply the patch.

What to do if your skin becomes red or irritated under or around the patch

As with any product that covers the skin for a period of time (such as bandages), the ESTALIS® patches can produce some skin irritation in some women. This varies according to the sensitivity of each woman.

Usually this redness does not pose any health concern to you, but to reduce this problem, you may change the site of application of the ESTALIS® patches every time a new patch is applied.

Experience with another patch, VIVELLE®, has shown that if you allow the patch to be exposed to the air for approximately 10 seconds after the protective liner has been removed, skin redness may not occur.

If redness and/or itching continues, you should consult your physician.

Always Remember
Your doctor has prescribed ESTALIS® for you after a careful review of your medical needs. Use it only as directed and do not give it to anyone else.

Use ESTALIS® within 6 months of purchase or before the expiry date shown on the pack, whichever comes first.

Do not use any ESTALIS® pack that is damaged or shows signs of tampering.
Do not expose the patch to direct sunlight.

Overdose:
Symptoms
Overdosage with estrogen may cause nausea, breast discomfort, fluid retention, bloating or vaginal bleeding in women.

Progestin (norethindrone acetate) overdosage may cause depressed mood, tiredness, acne and hirsutism.

If you suspect an overdose, remove the patch, contact either your doctor, or emergency department of the nearest hospital, or your regional poison control center immediately.

Missed Dose:
If you forget to change a patch, replace it with another patch as soon as you remember. No matter when this happens, go back to changing this patch on the day as specified on your initial schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Check with your doctor as soon as possible if any of the following occur:

Most Common Adverse Drug Reactions (≥1%)
- back pain or menstrual period-like pain,
- breast tenderness and excessive vaginal secretions (may be a sign that too much estrogen is taken), vaginal thrush (vaginal fungal infection with severe itching, vaginal discharge),
- change in weight,
- headache,
- intolerable breast tenderness,
- itching under the patch, reddening of the skin after the patch has been removed (signs of application site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, edema, erythema, inflammation, irritation, pain, tiny solid skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives, and blisters);
- nervousness,
- pain in extremity
- pelvic pain,
- persistent or severe skin irritation,
- rash, itching, acne, dryness

Less Common Adverse Drug Reactions (<1%)
- breast cancer, abnormal tumour growth related to estrogens (e.g. cancer of the lining of the womb – endometrial cancer)
- change in your sex drive,
- gall bladder disease (tendency to form gall stones) .
- painful and/or heavy periods (may be signs of growth of fibroids in uterus),
- or discoloration of the skin, purple skin patches,
- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention (oedema) persisting for more than 6 weeks,
- tingling or numbness,

Adverse Drug Reactions with unknown frequency

- tender, red nodules under the skin (most common on the shins)
- spotty darkening of the skin, particularly on the face or abdomen (chloasma),
- easy bruising,
- excessive nose bleeds,
- sudden contraction of the womb,
- hair loss,
- excessive hairiness,
- decline of memory or mental ability,
- rapid change in mood,
- difficulty sleeping,
- contact lens discomfort,
- dry eyes,
- hearing loss,
- itchy rash

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Frequency	**Symptom/possible side effect**	**Talk to your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
		Only if severe	**In all cases**	
Common	Abdominal pain, nausea or vomiting		**x**	
Uncommon	Breast lump		**x**	
	Crushing chest pain or chest heaviness			**x**
	Pain or swelling in the leg			**x**
	Persistent sad mood			**x**
	Sharp pain in the chest, coughing blood or sudden shortness of breath			**x**
	Sudden partial or complete loss of vision			**x**
	Sudden severe headache or worsening of headache,			**x**

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Frequency	**Symptom/possible side effect**	**Talk to your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
		Only if severe	**In all cases**	
	vomiting, dizziness, fainting, disturbance of vision or speech or weakness or numbness in an arm or leg			
	migraine			**x**
	Unexpected or excessively heavy vaginal bleeding		**x**	
	Yellowing of the skin or eyes (jaundice)			**x**
	Signs of a severe allergic reaction may include rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening, swelling of the face throat, lips, tongue, skin and periorbital edema.			**x**
	increase in blood pressure		**x**	

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

HOW TO STORE IT

ESTALIS® patches can be stored at room temperature (20- 25°C). In this case, use the patches within 6 months of purchase or before the expiry date shown on the pack, whichever comes first. You may also store the patches in a refrigerator (2-8°C), in which case you should use the patches before the expiry date shown on the pack and allow them to reach room temperature before you apply them.

Do not freeze. **Store in the original package.** ESTALIS® patches should be kept out of the reach and sight of children and pets before and after use.

REPORTING SUSPECTED SIDE EFFECTS

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

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

    Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

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

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

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc

Last revised: July 28, 2014

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd
Dorval, Quebec H9S 1A9

® Registered trademark