

Package leaflet: Information for the user

Lisvy 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch
gestodene/ethinylestradiol

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Lisvy is and what it is used for

Lisvy is a patch used to prevent pregnancy.

Each patch contains two different female hormones, namely gestodene and ethinylestradiol which are delivered continuously in small amounts over a period of 7 days.

Because Lisvy contains a combination of two hormones it belongs to the group of ‘combined hormonal contraceptives’.

2. What you need to know before you use Lisvy

General notes

Before you start using Lisvy you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 “Blood clots”).

Before you can begin using Lisvy, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Lisvy, or where the reliability of Lisvy may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Lisvy alters the monthly changes of body temperature and cervical mucus.

Lisvy, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Lisvy

You should not use Lisvy if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- If you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- if you need an operation or if you are off your feet for a long time (see section "Blood clots")
- if you have ever had a heart attack or stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms)
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
 - severe diabetes with blood vessel damage
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides)
 - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called ‘migraine with aura’
- if you have (or have ever had) liver disease (symptoms of which may be yellowing of the skin or itching over the whole body) and your liver is still not working normally
- if you have (or have ever had) a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- if you have (or have ever had) a benign or malignant tumour of the liver
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol, gestodene or any of the other ingredients of this medicine (listed in section 6). This may cause, for example, itching, rash or swelling.

If any of these conditions appear for the first time while using Lisvy, remove the patch immediately, stop using it and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also section 2 ‘General notes’ above.

Warnings and precautions

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see ‘Blood clot’ (thrombosis) section below.)

For a description of the symptoms of these serious side effects please go to “How to recognise a

blood clot”.

Talk to your doctor, pharmacist or nurse **before using Lisvy.**

In some situations you need to take special care while using Lisvy or any other combined hormonal contraceptive, and your doctor may need to examine you regularly.

Tell your doctor if any of the following conditions apply to you. If the condition develops, or gets worse while you are using Lisvy, you should also tell your doctor.

- If you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have a problem with your heart (valve disorder, disturbance of the heart rhythm)
- if anyone of your close relatives has ever had a blood clot (thrombosis in the leg, lung ‘pulmonary embolism’, or elsewhere), a heart attack or a stroke at a young age
- if you suffer from migraine
- if you have epilepsy (see section 2 ‘Other medicines and Lisvy’)
- if a close relative has (or has ever had) breast cancer
- if you have a disease of the liver or gall bladder
- if you have depression
- if you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system)
- if you have a haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).
- if you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clot’)
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using Lisvy.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, or Sydenham's chorea, a nerve disease causing sudden movements of the body)

- if you have (or have ever had) golden brown pigment patches (so-called ‘pregnancy patches’) especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- if you have hereditary angioedema. Consult your doctor **immediately** if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing oestrogens may induce or worsen symptoms of angioedema.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Lisvy increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Lisvy is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg e.g. turning pale, red or blue 	Deep vein thrombosis
<ul style="list-style-type: none"> • sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat; • severe pain in your stomach; <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a ‘common cold’).</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> • immediate loss of vision or • painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> • chest pain, discomfort, pressure, heaviness; • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats 	Heart attack

<ul style="list-style-type: none"> • sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	Stroke
<ul style="list-style-type: none"> • swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen) 	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of using a combined hormonal contraceptive for the first time. The risk may also be higher if you restart using a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Lisvy your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are using.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Lisvy is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined oral contraceptive that contains gestodene between about 9 and 12 women will develop a blood clot in a year.
- It is not yet known how the risk of a blood clot with Lisvy compares to the risk with a combined hormonal contraceptive that contains levonorgestrel and a combined oral contraceptive that contains gestodene.
- The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below).

	Risk of developing a blood clot in a year
Women who are not using a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using a combined oral contraceptive (pill) containing gestodene	About 9-12 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot during the use of Lisvy is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m²);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Lisvy may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Lisvy ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Lisvy needs to be stopped.

If any of the above conditions change while you are using Lisvy, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Lisvy is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Lisvy you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Lisvy, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

Combined hormonal contraceptives and cancer

Breast cancer has been observed slightly more often in women using combined hormonal contraceptives, but it is not known whether this is caused by the treatment itself. For example, it may be that more tumours are detected in women on combined hormonal contraceptives because they are examined by their doctor more often. The risk of breast tumours becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, **benign liver tumours**, and in even fewer cases **malignant liver tumours** have been reported in combined hormonal contraceptive users. In isolated cases, these tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

The most important risk factor for **cervical cancer** is persistent Human Papilloma Virus (HPV) infection. Some studies suggest that long-term use of combined hormonal contraceptives increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus increases this risk.

Bleeding between periods

With all combined hormonal contraceptives, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to use Lisvy as normal.

Irregular vaginal bleeding usually stops once your body has adjusted to Lisvy (usually after about 3 cycles). If it continues, becomes heavy or starts again, tell your doctor.

What to do if no bleeding occurs

If you have used Lisvy correctly and have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to use Lisvy as usual.

If you have used Lisvy incorrectly, or, if you have used Lisvy correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not continue with the next patch until you are sure that you are not pregnant. In the meantime, use non-hormonal contraceptive measures. See also section 2 'General notes' above.

Children and adolescents

Safety and efficacy of Lisvy have not been demonstrated in adolescents under 18 years of age.

Other medicines and Lisvy

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or herbal products, including medicines obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist from whom you got the medicine) that you use Lisvy. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines can have an influence on the blood levels of Lisvy and can make it **less effective in preventing pregnancy**, or can cause unexpected bleeding. These include:

- medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, eslicarbazepine, topiramate, felbamate)
 - tuberculosis (e.g. rifampicin, rifabutin)
 - sleep disorder narcolepsy (modafinil)
 - high blood pressure in the blood vessels in the lungs (bosentan)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors), such as ritonavir, nevirapine, efavirenz or other infections (griseofulvin).
- the herbal remedy St. John's wort

Combined hormonal contraceptives may influence the **effect of other medicines** such as the anti-epileptic lamotrigine.

Laboratory tests

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are using Lisvy because hormonal contraceptives can affect the results of some tests.

Lisvy with food, drink and alcohol

It is not expected that food, drink or alcohol will affect the way Lisvy works.

Pregnancy and breast-feeding

Do not use Lisvy if you are pregnant, or, if you think you may be pregnant. If you become pregnant while using Lisvy, remove it immediately and contact your doctor.

If you want to become pregnant, you can stop using Lisvy at any time (see also section 3 ‘If you stop using Lisvy’).

Lisvy is generally not recommended for use during breast-feeding. If you want to use Lisvy while you are breast-feeding you should contact your doctor.

Driving and using machines

You can drive or operate machinery while using Lisvy.

3. How to use Lisvy

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Lisvy prevents you from becoming pregnant by transferring hormones to your body through your skin. The patch must stick securely to your skin in order for it to work properly.

The efficacy of Lisvy depends on how well you follow the instructions for using the patch. The more closely you follow these instructions, the less chance you have of getting pregnant.

Therefore, always use Lisvy exactly as described in this booklet. **If you do not follow these instructions, you may increase your risk of getting pregnant.**

When to start Lisvy for the first time

Make a note of which day of the week you apply your **first** patch. This weekday will become your weekly '**Patch Change Day**' (see the section on ‘Patch Change Day’ below in this section 3).

Follow the rules for **starting or switching** to Lisvy by selecting the contraceptive method used in the **previous** month in the left column of the following table:

Rules for starting or switching to Lisvy

Contraceptive method used in previous month	Rules for starting or switching to Lisvy
No hormonal contraceptive	Start using Lisvy on the first day of your natural cycle (Day 1 of your period). Lisvy will work immediately and it is not necessary to use an additional contraceptive method. You may also start wearing a patch on Days 2-5 of your cycle, but you must make sure you also use an additional contraceptive method (e.g. condom) during the 7 days of wearing the first patch.

Contraceptive method used in previous month	Rules for starting or switching to Lisvy
Combined hormonal contraceptive pill	<p>We recommend you to start using Lisvy the day AFTER you take the last hormone-containing tablet from your pill pack. This means no tablet-free break. If your pill pack also contains hormone-free tablets you can start Lisvy on the day AFTER taking the last tablet containing hormones. If you are not sure which this is, ask your doctor or pharmacist.</p> <p>You can also start later, but never start later than the first day after the end of the break of your pill (or the first day after the last hormone-free tablet of your pill).</p>
Combined contraceptive vaginal ring	<p>Start using Lisvy on the day of removal of the last ring of a cycle pack, but at the latest when the next application would have been due.</p>
Combined contraceptive patch	<p>Start using Lisvy on the day of removal of the last patch of a cycle pack, but at the latest when the next application would have been due.</p>
Progestogen-only pill (“Minipill”)	<p>You can switch to Lisvy on any day without a break.</p> <p>You must use extra protective measures (e.g. condom) during the 7 days of wearing the first patch.</p>
Progestogen-only implant	<p>Start using Lisvy on the day of removal.</p> <p>You must use extra protective measures (e.g. condom) during the 7 days of wearing the first patch.</p>
Progestogen-releasing intrauterine system	<p>Start using Lisvy on the day of removal.</p> <p>You must use extra protective measures (e.g. condom) during the 7 days of wearing the first patch.</p>
Progestogen-only injection	<p>Start using Lisvy on the day when the next injection would have been due.</p> <p>You must use extra protective measures (e.g. condom) during the 7 days of wearing the first patch.</p>

After a miscarriage

Follow the advice of your doctor.

After having a baby

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start using Lisvy. Sometimes it is possible to start sooner. Your doctor will advise you.

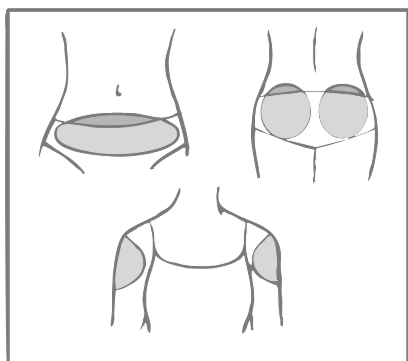
If, after having a baby, you have had sex before starting Lisvy, be sure that you are not pregnant or wait until your next menstrual period before applying the patch.

If you want to start Lisvy after having a baby and are breast-feeding, discuss this first with your doctor.

Ask your doctor what to do if you are not sure when to start using Lisvy.

Where to apply the patch

Use Lisvy only on the following sites: abdomen, buttocks or outer upper arm, **in a place where it will not be rubbed off by tight clothing** (see figure below). For example, do NOT place the patch at the waistband of your clothing.



Make sure your skin at the application site is unbroken, healthy, clean, dry, and preferably hairless. Do NOT put the patch on your breasts, on cut, red or irritated skin, or in the same place you put your last patch.

Do NOT use lotions, creams, oils, powders, make-up or other products on the skin area where the patch is or will be placed. **It may stop the patch sticking properly or cause it to become loose.**

Vary where you place the patch by using different areas at the same application site. For example, you can change from left to right side of the abdomen or from left to right buttock or upper arm.

You can also use a different application site each week (e.g. one week the outer upper arm, next week the abdomen).

Check your patch daily to ensure that it is sticking securely to your skin.

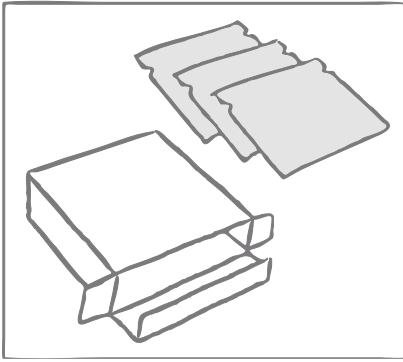
Please note

- Only wear ONE patch at a time.
- If your patch is applied correctly, you can bathe or shower as usual.
- There are no restrictions such as swimming, using a sauna and exercising as long as the patch remains applied correctly.
- The transparent patch is UV/sunlight protected so it can be exposed to sunlight and does not need to remain covered by clothing.

What did you receive in the pharmacy

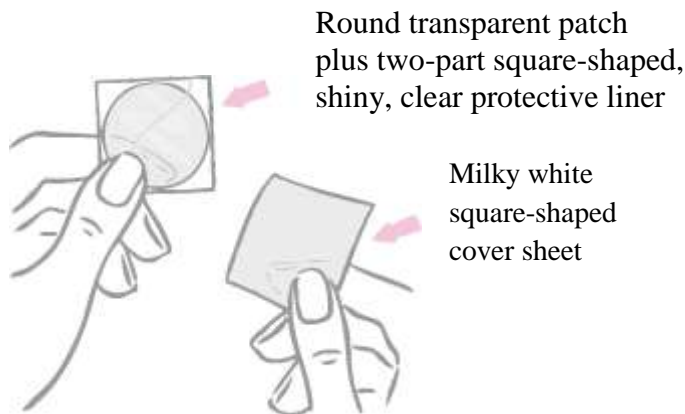
At the pharmacy you received a Lisvy box which includes this booklet plus either 3 or 9 or 18 sealed sachets, each containing one Lisvy patch.

The number of sachets depends on the prescription your doctor has given you.



Each sealed sachet contains one patch, for application onto your skin. The patch is round and transparent:

- On its **sticky side** the patch is covered by a **two-part square-shaped shiny clear protective liner**
- On the **opposite side** the patch is covered by a **milky white square-shaped cover sheet** which prevents the patch from being stuck in the sachet



Round transparent patch
plus two-part square-shaped,
shiny, clear protective liner

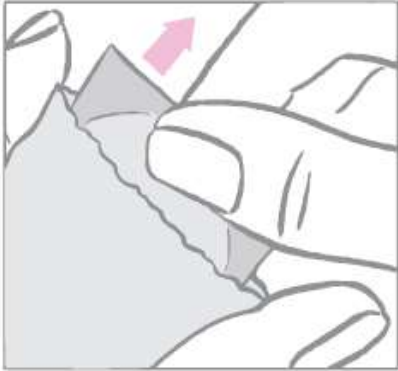
Milky white
square-shaped
cover sheet

How to prepare the patch for application

1. Tear along the top side of the sachet with your fingers. The notches will help guide the tear.
Do not use scissors. Do not cut, damage or alter the patch in any way because this may reduce the contraceptive effect.

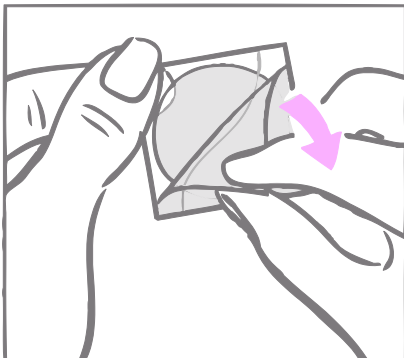


2. The round contraceptive patch is enclosed between a two-part square-shaped clear protective liner and a milky-white square shaped cover sheet. It is important you remove the patch together with both the clear protective liner and the milky-white cover sheet from the sachet. **Do not discard the sachet. The sachet should be kept for disposal of the patch after use** (see ‘Disposal of patches’ in section 5).



3. Apply the patch **immediately** after opening the sachet, as follows:

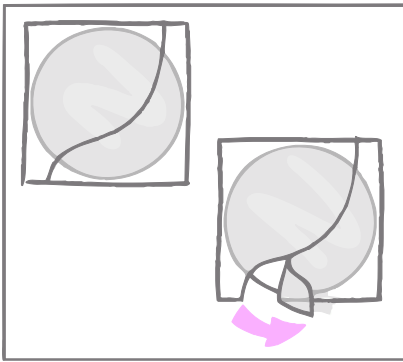
- First remove the one-piece milky white square-shaped cover sheet from the top side of the patch.



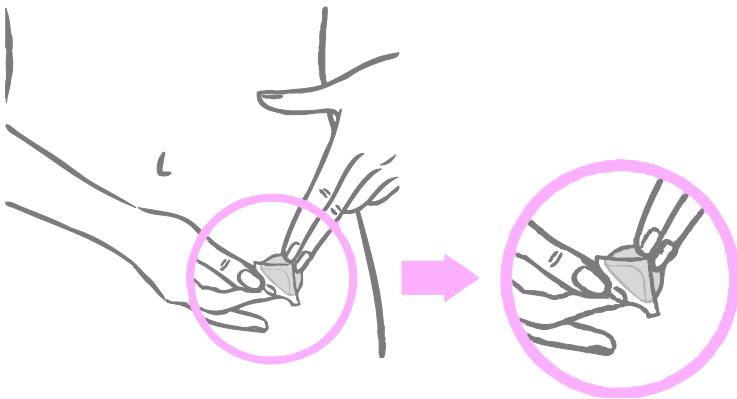
After removal from the patch, the milky white square-shaped cover sheet that prevents the patch from getting stuck in the sachet should be discarded.

The two-part square-shaped shiny clear protective liner covers the bottom (sticky) side of the round transparent patch. The sticky side contains the active drugs. **You should avoid touching the sticky surface of the patch so that the stickiness is maintained.**

- Next remove half of the clear protective liner.



- While holding the patch by the edge which is still covered by the second half of the protective liner, position the patch on the skin where it will be worn.
- With half of the patch gently sticking to the application site, remove the second half of the protective liner.



- Press down firmly on the patch with the palm of your hand for 30 seconds. Make sure that the edges stick well.



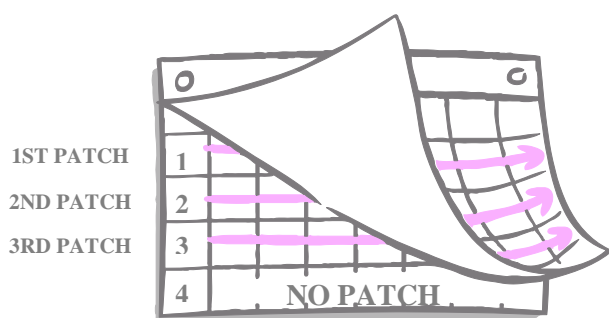
Remember not to discard the sachet as you will need it to dispose of the patch after use (see ‘Disposal of patches’ in section 5).

Instructions on further use

Each patch should be used as follows: For three consecutive weeks, one patch is used for a period of 1 week. After the 3 weeks in which a patch is used, the 7-day patch-free interval make up a 4-week cycle.

CALENDAR							
WEEK	MON	TUE	WED	THU	FRI	SAT	SUN
1ST PATCH	1						
2ND PATCH	2						
3RD PATCH	3						
4	NO PATCH						

- Apply a new patch on the **same day** each week (your 'Patch Change Day' – see 'Patch Change Day' below in this section 3) for 3 weeks in a row.
- Make sure you have removed your old patch **before** applying the new patch because only one patch should be worn at a time.
- Be sure to use a different application area for each new patch.
- During week 4, **DO NOT** wear a patch. Make sure you removed your old patch. Your period should begin during this week. If your period does not occur, see section 2 'What to do if no bleeding occurs'. For the precise scheme when to apply/remove a patch, see section 'Patch Change Day' below in this section 3.
- On the day after week 4 ends, start a new 4-week cycle on the same weekday by applying a new patch ('Patch Change Day'), regardless of whether your period is continuing or has stopped.



- Repeat the same steps every 4 weeks.

Patch Change Day

Apply every new patch on the **same day** of the week. This day will be your 'Patch Change Day'. For example, if the first patch is applied on a Sunday, all subsequent patches will also be applied on a Sunday. Wear only one patch at a time.

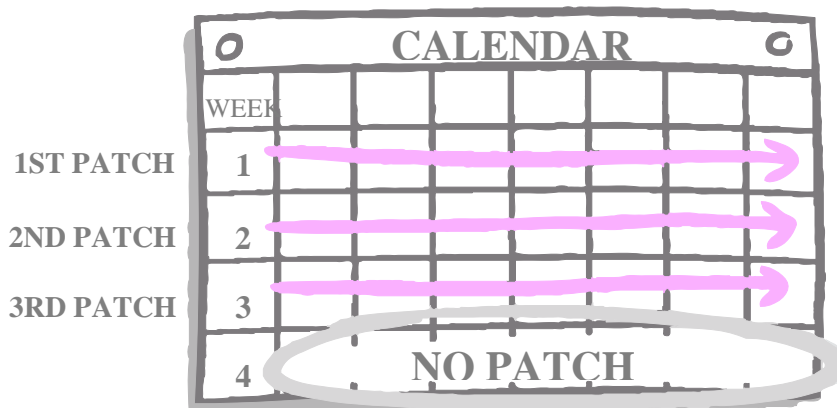
- 1st patch** **Week 1** (cycle Day 1): application of the 1st patch
- 2nd patch** **Week 2** (cycle Day 8): removal of the 1st patch and immediate application of the 2nd patch
- 3rd patch** **Week 3** (cycle Day 15): removal of the 2nd patch and immediate application of the 3rd patch
- No patch** **Week 4** (cycle Day 22): removal of the 3rd patch, **no patch** from cycle Days 22-28!

You may change your patch at any time on the 'Patch Change Day'.

Start your next cycle on the same 'Patch Change Day', at the end of the 7-day patch-free interval (Days 22-28).

Patch-free days

Do not wear a patch during week 4 (from cycle Days 22 – 28).



You must never have your patch off for more than 7 consecutive days.

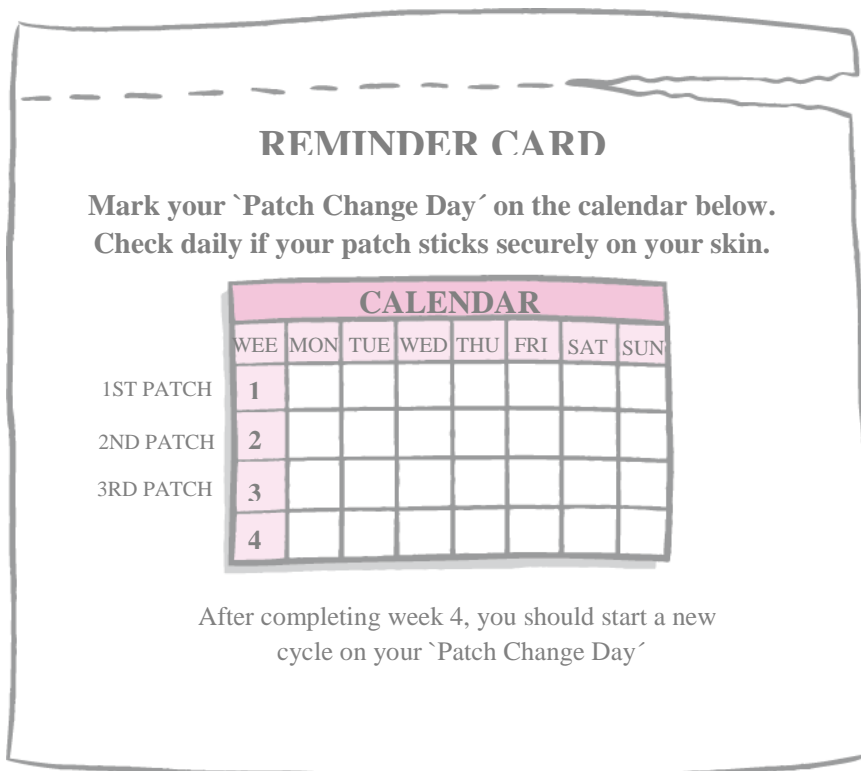
If you have more than 7 patch-free days, YOU MAY NOT BE PROTECTED FROM PREGNANCY.

If you have had sex during such an extended patch-free interval, you already may have become pregnant. Use back-up contraception, for example condoms (see also ‘What you should do in case of detached, missed, or not replaced patches’ later on in this section 3).

Reminder card and reminder stickers

To help you remember the ‘Patch Change Day’, you may find the detachable reminder card and reminder stickers at the end of this booklet useful.

On the reminder card, you can highlight your ‘Patch Change Day’ for the 4-week cycle. You can also use the reminder stickers provided to mark your personal calendar or diary.



The reminder sticker with the tick symbol should be placed on the day you apply your 1st patch in week 1 – this is your 'Patch Change Day'.



The two reminder stickers with the arrow symbols should be placed on your 'Patch Change Days' in weeks 2 and 3.



The sticker with the cross symbol should be placed on your 'Patch Change Day' in week 4. During week 4, **DO NOT** wear a patch.



After you have completed the 4-week cycle, you should repeat the steps above.

If you use more Lisvy than you should

Lisvy is unlikely to cause an overdose because the patch releases a steady amount of the hormones. Do not use more than one patch at a time. Serious side effects have not been reported when large doses of hormonal contraceptives were accidentally taken.

Overdose by applying several patches at a time may cause nausea or vomiting.

Young girls may have bleeding from the vagina. In case of overdose, contact your doctor or pharmacist.

If you forget to use Lisvy

What you should do in case of detached, missed, or not replaced patches:

If a patch is partially or completely detached

- *for less than one day (up to 24 hours)*

You should try to reapply the patch to the same place or replace it with a new patch immediately. No back-up contraception is needed. Your 'Patch Change Day' will remain the same.

- *for more than one day (24 hours or more), or if you are not sure how long the patch has been detached*

YOU MAY NOT BE PROTECTED FROM PREGNANCY. Stop the current contraceptive cycle and start a new cycle immediately by applying a new patch. You now have a new 'Day 1' and a new 'Patch Change Day'. You must use back-up contraception, such as condoms, spermicide, or diaphragm, for the first week of the new cycle.

Do not reapply a patch if it is no longer sticky, if it has become stuck to itself or another surface, if it has other material stuck to it or if it has previously become loose or fallen off. If you cannot reapply a patch, apply a new patch immediately. Do not use other adhesives or wraps to hold Lisvy in place.

If you forget to change your patch

- *at the start of any patch cycle*
(Week One /Day 1):

YOU MAY NOT BE PROTECTED FROM PREGNANCY. Apply the first patch of your new cycle as soon as you remember. You now have a new 'Patch Change Day' and a new 'Day 1'. You must use back-up contraception, such as condoms, spermicide, or diaphragm, for the first week of the new cycle.

- *in the middle of the patch cycle*
(Week Two/Day 8 or Week Three/Day 15):

- If you are late for one or two days (**up to 48 hours**),
apply a new patch immediately. Apply the next patch on your usual 'Patch Change Day'. No back-up contraception is needed.

- If you are late for more than two days (**48 hours or more**),

YOU MAY NOT BE PROTECTED FROM PREGNANCY. Stop the current contraceptive cycle and start a new 4-week cycle immediately by putting on a new patch. You now have a new 'Patch Change Day' and a new 'Day 1'. Use back-up contraception for one week.

- *at the end of the patch cycle*
(**Week Four/Day 22**):

If you forget to remove your patch, take it off as soon as you remember (at the latest by Day 28). Start the next cycle on your usual ‘Patch Change Day’, which is the day after Day 28. No back-up contraception is needed.

The consequences of detached, missed, or not replaced patches and what you should do is presented in the following table:

Consequences of detached, missed, or not replaced patches and required action

Detached patches ^a	Time frame	Consequences on contraceptive reliability ^a	Required action ^a
Patch detached	< 24 hours	Contraceptive efficacy ensured	- Apply new patch immediately - No back-up contraception needed - ‘Patch Change Day’ unchanged
	> 24 hours	Contraceptive efficacy compromised	- Start new 4-week cycle immediately by applying a new patch - Use back-up contraception for the next 7 days ^b - Note new ‘Patch Change Day’
Patches not replaced on time ^a	Time frame	Consequences on contraceptive reliability ^a	Required action ^a
1 st patch (Week 1, Day 1) not applied on time	1 st patch not applied on ‘Patch Change Day’	Contraceptive efficacy compromised	- Start new 4-week cycle immediately by applying a new patch - Use back-up contraception for the next 7 days ^b - Note new ‘Patch Change Day’
1 st or 2 nd patch (Week 1/2 or 2/3) not replaced on time	< 48 hours	Contraceptive efficacy ensured	- Apply new patch immediately - No back-up contraception needed - ‘Patch Change Day’ unchanged
	> 48 hours	Contraceptive efficacy compromised	- Start new 4-week cycle immediately by applying a new patch - Use back-up contraception for the next 7 days ^b - Note new ‘Patch Change Day’
3 rd patch (Week 3/4) not removed on time		Contraceptive efficacy ensured ^c	- Remove patch - Start next 4-week cycle on your normal ‘Patch Change Day’
^a Applies to each cycle. ^b Back-up contraception is any additional non-hormonal method of contraception with the exception of the ‘calendar’ method and the ‘temperature’ method. ^c Provided that the 3 rd patch has been replaced by a new one at the latest on the regular Day 1 of the new patch cycle.			

Order the prescription of the next pack in time i.e. prior to the use of the last patch in the pack to ensure that you do not run out of patches.

What to do in case of skin irritation

If patch use results in uncomfortable irritation at the site of the patch, remove the patch and place a new patch on a different location. Use the new patch until the next scheduled 'Patch Change Day'.

How to shift your 'Patch Change Day' to another day

If you wish to shift your 'Patch Change Day', complete your current cycle and remove the third patch on the correct day. During the patch-free week, you may select an earlier (never a later) 'Patch Change Day' by applying a new patch on your desired day. You must never have your patch off for more than seven days.

What to do if you vomit or have severe diarrhoea

The amount of drug you get from Lisvy should not be affected by vomiting or diarrhoea.

If you stop using Lisvy

You can stop using Lisvy at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop using Lisvy and wait for a menstrual period before starting to try to become pregnant. You will be able to calculate the expected delivery date more easily.

You may get irregular, little or no menstruation if you stop using Lisvy, especially if your periods were not regular before you started to use Lisvy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lisvy can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Lisvy, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 'What you need to know before you use Lisvy'.

Serious side effects

See section 2 'Warnings and precautions, Blood clots and Combined hormonal contraceptives and cancer' for side effects, including serious reactions, associated with the use of combined hormonal contraceptives and section 2 'Do not use Lisvy'. Please read these sections carefully and consult your doctor at once where appropriate.

The following side effects were reported in Lisvy users:

Very common: may affect more than 1 in 10 women

- application site reaction

Common: may affect up to 1 in 10 women

- emotional lability
- migraine
- nausea
- genital tract bleeding

- breast pain

Uncommon: may affect up to 1 in 100 women

- depression/depressive mood
- decrease and loss of libido

Rare: may affect up to 1 in 1,000 women

- harmful blood clots in a vein or artery

Not known: cannot be estimated from the available data

- skin reactions such as skin redness, skin itching and skin irritation outside the application site

Description of selected side effects

Side effects with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined hormonal contraceptives are listed below (see also section 2 ‘Do not use Lisvy’ and ‘Warnings and precautions’):

Blood clots

- harmful blood clots in a vein or artery for example:
 - in a leg or foot (i.e. DVT)
 - in a lung (i.e. PE)
 - heart attack
 - stroke
 - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
 - blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

Tumours

- The frequency of diagnosis of breast cancer is very slightly increased among users of combined hormonal contraceptives. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. It is not known whether there is a direct link to users of combined hormonal contraceptives.
- liver tumours (benign and malignant)

Other conditions

- a skin condition characterised by itchy red blotches or swollen patches of skin (erythema multiforme)
- a skin condition characterised by tender red nodules (erythema nodosum)
- increased blood fats (hypertriglyceridemia, resulting in an increased risk of pancreatitis when using combined hormonal contraceptives)

- high blood pressure
- occurrence or worsening of conditions for which a link to combined hormonal contraceptives is not definite: jaundice and/or itching related to blocked bile flow (cholestasis); gallstone formation; a metabolic condition called porphyria; systemic lupus erythematosus (disease of the immune system); haemolytic uraemic syndrome (a blood clotting disorder causing failure of the kidneys); a nerve disease causing sudden movements of the body called Sydenham's chorea; herpes gestationis (a type of skin condition that occurs during pregnancy); hearing loss
- in women with hereditary angioedema (characterised by sudden swelling of e.g. the face, tongue or throat) external oestrogens may induce or worsen symptoms of angioedema
- disturbed liver function
- changes in glucose tolerance or effect on peripheral insulin resistance
- worsening of inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- worsening of epilepsy
- golden brown pigment patches (so-called 'pregnancy patches' especially on the face)
- hypersensitivity (including symptoms such as rash, hives)

Interactions

Unexpected bleeding and/or contraceptive failure may result from interactions of other medicines with combined hormonal contraceptives (e.g. the herbal remedy St. John's wort, or medicines for epilepsy, tuberculosis, HIV and Hepatitis C Virus infections). See section 2 'Other medicines and Lisvy'.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRa Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517

Website: www.hpra.ie

email: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Lisvy

Keep this medicine out of the sight and reach of children.

Store in the original sachet in order to protect from light and moisture.

Do not use Lisvy after the expiry date, which is stated on the folding box and sachet label after EXP. The expiry date refers to the last day of that month.

Disposal of patches and other handling

The patch should be applied immediately upon removal from the protective sachet.

No make-up, creams, lotions, powders or other topical products should be applied to the skin area where Lisvy is or will be placed.

The active substances gestodene and ethinylestradiol pose a risk to the environment, especially to fish. Moreover, gestodene and ethinylestradiol are persistent in the environment. Used patches should not be flushed down the toilet nor placed in liquid waste disposal systems.

The used patch should be discarded carefully according to the following instructions:

- Keep the original sachet after use for disposal of the patch.
- Fold the used patch in half, adhesive/sticky side inwards.
- Place it in the original sachet.
- Close by folding the open edge.
- There is a two page label on the sachet.
- Lift the first page of the label and use it to seal the folded edge of the sachet.
- Below the first page, disposal instructions can be found on the second page.

Discard safely out of the reach of children or pets. Any used or unused patches should be discarded according to local requirements. In case of doubt consult your pharmacist. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lisvy contains

The **active substances** are gestodene and ethinylestradiol. Each 11 cm² transdermal patch contains 2.10 mg gestodene and 0.55 mg ethinylestradiol.

Each transdermal patch releases 60 micrograms gestodene per 24 hours and 13 micrograms ethinylestradiol (equal to oral dose of 20 micrograms) per 24 hours.

The **other excipients** in the patch are:

Backing layer: low density polyethylene (PE) outer layer

Adhesive layer: adhesive containing: ester of hydrogenated rosin, polybutene, polyisobutylene, pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), bemotrizinol

Separation foil: polyethylene terephthalate (PET) film

Adhesive matrix: adhesive containing: ester of hydrogenated rosin, polybutene, polyisobutylene, pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)

Release liner: siliconized polyethylene terephthalate (PET) film.

What Lisvy looks like and contents of the pack

A Lisvy folding box contains: this booklet (including reminder card and reminder stickers) plus either 3, 9 or 18 sealed sachets; each sachet contains one transdermal patch.

Not all pack sizes may be marketed.

The thin transdermal patch is round, transparent, and has a size of 11 cm²:

- On its sticky side the patch is covered by a two-part square-shaped shiny clear protective liner.
- On the opposite side the patch is covered by a milky white square-shaped cover sheet which prevents the patch from being stuck in the sachet.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest, Hungary

Manufacturer

Bayer Weimar GmbH und Co. KG
99427 Weimar
Germany

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Proposed (invented) name, strength, and pharmaceutical form
Austria (AT)	Lisvy 60 Microgramm/24 h + 13 Microgramm/24 h transdermales Pflaster
Belgium (BE)	Lisvy 60 microgram/24 uur + 13 microgram/24 uur pleister voor transdermaal gebruik
Bulgaria (BG)	Лизви 60 микрограма/24 часа + 13 микрограма/24 часа Lisvy 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch
Cyprus (CY)	Lisvy 60 μικρογραμμάρια/24 ώρες + 13 μικρογραμμάρια/24 ώρες διαδερμικό έμπλαστρο
Czech Republic (CZ)	Lisvy 60 mikrogramů/24 hodin + 13 mikrogramů/24 hodin transdermální náplast
Denmark (DK)	Lisvy 60 mikrogram/24 timers + 13 mikrogram/24 timers depotplaster

Estonia (EE)	Eileen 60 mikrogrammi/24 tunnis + 13 mikrogrammi/24 tunnis transdermaalne plaaster
Finland (FI)	Lisvy 60 mikrog/24 tuntia + 13 mikrog/24 tuntia depotlaastari
France (FR)	Lisvy 60 microgrammes/24 heures + 13 microgrammes/24 heures dispositif transdermique
Germany (DE)	Lisvy, 60 Mikrogramm/24 Stunden + 13 Mikrogramm/24 Stunden, Transdermales Pflaster
Greece (EL)	Lisvy 60 μικρογραμμάρια/24 ώρες + 13 μικρογραμμάρια/24 ώρες διαδερμικό έμπλαστρο
Hungary (HU)	Lisvy 60 mikrogramm/24 óra + 13 mikrogramm/24 óra transzdermális tapasz
Iceland (IS)	Lisvy 60 míkrogrömm/24 klst + 13 míkrogrömm/24 klst forðaplástur
Ireland (IE)	Lisvy 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch
Italy (IT)	Enciela 60 microgrammi/24 ore + 13 microgrammi/24 ore cerotto transdermico
Latvia (LV)	Eileen 60 mikrogrami/24 stundās + 13 mikrogrami/24 stundās transdermāls plāksteris
Lithuania (LT)	Eileen 60 mikrogramų/24 val. + 13 mikrogramų/24 val. transderminis pleistras
Luxembourg (LU)	Lisvy 60 microgrammes/24 heures + 13 microgrammes/24 heures dispositif transdermique
Malta (MT)	Lisvy 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch
The Netherlands (NL)	Lisvy 60 microgram/24 uur + 13 microgram/24 uur pleister voor transdermaal gebruik
Poland (PL)	Lisvy 60 mikrogramów/24 godziny + 13 mikrogramów/24 godziny system transdermalny plaster
Portugal (PT)	Lisvy 60 microgramas/24 horas + 13 microgramas/24 horas Sistema transdémico
Romania (RO)	Lisvy 60 micrograme/24 ore + 13 micrograme/24 ore plasture transdermic

Slovak Republic (SK)	Lisvy 60 mikrogramov/24 hodín + 13 mikrogramov/24 hodín transdermálna náplast'
Slovenia (SI)	Lisvy 60 mikrogramov/24 ur + 13 mikrogramov/24 ur transdermalni obliž
Spain (ES)	Lisvy 60 microgramos cada 24 horas + 13 microgramos cada 24 horas parche transdérmico
United Kingdom (UK)	Lisvy 60 micrograms/24 hours + 13 micrograms/24 hours transdermal patch

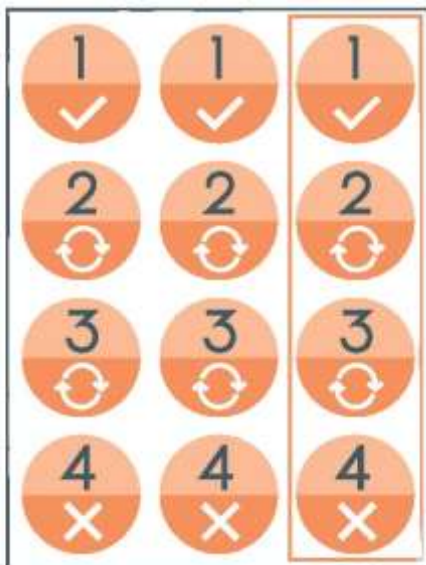
This leaflet was last revised in 01/2018

<Reminder stickers>

<3 transdermal patches>

<9 transdermal patches>

Place these reminder stickers on your calendar or diary and read section on 'reminder card and reminder stickers'.



<Reminder card>

REMINDER CARD

Mark your 'Patch Change Day' on the calendar below.
Check daily if your patch sticks securely on your skin.

CALENDAR							
WEEK	MON	TUE	WED	THU	FRI	SAT	SUN
1ST PATCH	1						
2ND PATCH	2						
3RD PATCH	3						
4							

After completing week 4, you should start a new cycle on your 'Patch Change Day'.