Package leaflet: Information for the user

Estraderm MX 25, 50, 75 and 100

oestradiol (as hemihydrate)

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Estraderm MX is and what it is used for**
2. **What you need to know before you use Estraderm MX**
3. **How to use Estraderm MX**
4. **Possible side effects**
5. **How to store Estraderm MX**
6. **Contents of the pack and other information**

1. What Estraderm MX is and what it is used for

Estraderm MX is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. Estraderm MX is used in postmenopausal women with at least 12 months since their last natural period.

Estraderm MX is a patch that is applied to the skin. The patch contains a supply of oestradiol which is released from the patch and absorbed through the skin into your blood stream. This is called a transdermal patch.

Estraderm MX is used for:

Relief of symptoms occuring after menopause
During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest (hot flushes). Estraderm MX alleviates these symptoms after menopause. You will only be prescribed Estraderm MX if your symptoms seriously hinder your daily life.

Prevention of osteoporosis (for Estraderm MX 50 and 75 only)
After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor.
If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Estraderm MX to prevent osteoporosis after menopause.

2. What you need to know before you use Estraderm MX

Medical history and regular check-ups
The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on Estraderm MX you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Estraderm MX.

Go for regular breast screening, as recommended by your doctor.

Do not take Estraderm MX
if any of the following applies to you. If you are not sure about any of the points below, talk to your doctor before taking Estraderm MX,

Do not take Estraderm MX
- If you have or have ever had **breast cancer**, or if you are suspected of having it
- If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have any **unexplained vaginal bleeding**
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- If you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- If you have a rare blood problem called 'porphyria' which is passed down in families (inherited)
- If you are **allergic** to oestradiol or any of the other ingredients of this medicine (listed in section 6).

If any of the above conditions appear for the first time while taking Estraderm MX, stop taking it at once and consult your doctor immediately.

Warnings and precautions

Take special care with Estraderm MX

If you experience:
- difficulty breathing or swallowing, tightness of the chest, hives, general rash, swelling, itching, dizziness, vomiting, abdominal pain (possible signs of a severe allergic reaction) or
- swelling of the face, lips, tongue, throat, and/or extremities (possible signs of angioedema)

Stop using Estraderm MX and tell your doctor immediately.

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Estraderm MX. If so, you should see your doctor more often for check-ups:
- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see Blood clots in a vein (thrombosis))

- increased risk of getting a oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- hereditary and acquired angioedema
- Do you have hypothyroidism (a condition in which your thyroid gland fails to produce enough thyroid hormone and for which you are treated with thyroid hormone replacement therapy)?
- Do you have hereditary angioedema or if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract?

Stop taking Estraderm MX and see a doctor immediately
If you notice any of the following when taking HRT:
- any of the conditions mentioned in the 'DO NOT take Estraderm MX' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness).
- migraine-like headaches which happen for the first time.
- if you become pregnant
- if you notice signs of a blood clot, such as:
  - painful swelling and redness of the legs
  - sudden chest pain
  - difficulty in breathing

For more information, see 'Blood clots in a vein (thrombosis)'

Note: Estraderm MX is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)
Taking oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

Taking a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk. So your doctor will prescribe a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

In women who still have a womb and who are not taking HRT, on average, 5 in 1000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a womb and who take oestrogen-only HRT, between 10 and 60 women in 1000 will be diagnosed with endometrial cancer (i.e. between 5 and 55 extra cases), depending on the dose and for how long it is taken.

Estraderm MX 75 and Estraderm MX 100 contains a higher dose of oestrogens than other oestrogen-only HRT products. The risk of endometrium cancer when using Estraderm MX together with a progestogen is not known.

Breast cancer
Evidence shows that taking combined oestrogen-progestogen and possibly or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The risk is much lower in women taking oestrogen-only HRT than in those taking oestrogen-progestogen combinations. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare
Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period.
For women aged 50 who start taking oestrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases).
For women aged 50 who start taking oestrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period.
For women aged 50 who start taking oestrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases)
For women aged 50 who start taking oestrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

- **Regularly check your breasts. See your doctor if you notice any changes such as:**
  - dimpling of the skin
  - changes in the nipple
  - any lumps you can see or feel

Ovarian cancer
Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)
The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery)
- you are seriously overweight (BMI >30 kg/m2)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

For signs of a blood clot, see 'Stop taking Estraderm MX and see a doctor immediately'.

Compare
Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking oestrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

For women in their 50s who have had their womb removed and have been taking oestrogen-only HRT for over 5 years, there will be 5 to 8 cases in 1000 users (i.e. 1 extra case).

Heart disease (heart attack)
There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

For women who have had their womb removed and are taking oestrogen-only therapy there is no increased risk of developing a heart disease.

Stroke
The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Compare
Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Other conditions
- HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Other medicines and Estraderm MX
Some medicines may interfere with the effect of Estraderm MX. This might lead to irregular bleeding. This applies to the following medicines:
- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine);
- Medicines for **tuberculosis** (such as rifampicin, rifabutin);
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir);
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*).

HRT can affect the way some other medicines work:
- A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures
- Medicines for **Hepatitis C virus** (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Estraderm MX contains

estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Estraderm MX with this HCV combination regimen.
- Other **anti-infective medicines** (such as ketoconazole, erythromycin).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking Estraderm MX, because this medicine can affect the results of some tests. Some laboratory tests, such as tests for glucose tolerance or thyroid function, may be affected by Estraderm MX therapy.

Pregnancy and breast-feeding
Estraderm MX is for use in postmenopausal women only. If you become pregnant, stop taking Estraderm MX and contact your doctor.

Estraderm MX should not be used during breast-feeding.

Driving and using machines
Estraderm MX has no known effect on the ability to drive and use machines.

3. How to use Estraderm MX

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

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

If you have not had a hysterectomy, your doctor will give you tablets containing another hormone called progestogen to offset the effects of oestrogens on the lining of the womb. (See the section above on ovarian cancer.) Your doctor will explain to you how to take these tablets. Withdrawal bleeding may occur at the end of the progestogen treatment period. Tell your doctor if you get irregular and/or heavy bleeding (see ovarian cancer).

When to start treatment
- If you are not currently using any form of HRT (patch or tablets), if you have had a hysterectomy or if you have been using a continuous combined HRT product (where oestrogen and the progestogen are given every day without interruption), you can start to use Estraderm MX on any convenient day.
- If you are changing from a cyclic or sequential HRT treatment (where the progestogen is added for 12-14 days of the cycle), start to use Estraderm MX the day after you complete the cycle.
- If you are still having periods you should start to use Estraderm MX within 5 days of starting your period, irrespective of how long you bleed.

How long to use Estraderm MX
It is important that you use the lowest possible effective dose and only as long as needed. You should apply a new patch twice a week i.e. every 3 or 4 days.

From time to time, you should discuss with your doctor whether you still need the treatment

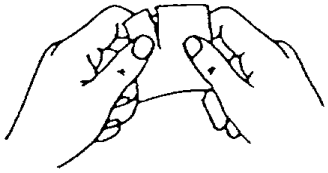
Where to apply Estraderm MX
- Estraderm MX patches are applied to the skin. You wear them all the time.

Stick the patch on to a hairless area of skin below the waist. Most patients find that the buttock is the best place. Choose an area of the buttock where the skin is not inflamed, broken, or irritated. You could also try the lower back, hip or abdomen.

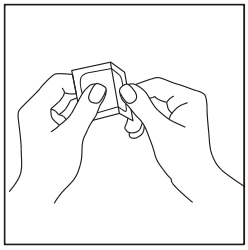
Never put a patch on or near the breasts.

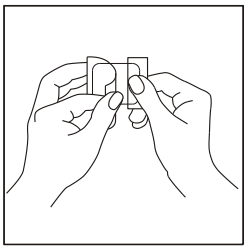
Choose a clean, dry area of skin. To help the patch stick, the skin should be clean, dry, and free of creams, lotions, oil, or powder. You should use a different area of skin each time. Wait a week before using the same area again. Avoid skin which is red or irritated.
Do not expose the patch to direct sunlight.

How to apply Estraderm MX
Each Estraderm MX patch is sealed in an airtight sachet. Tear open one of the sachets at the notch (do not use scissors) and take out the patch. Don't take the patch out of the sachet until immediately before you intend to use it.



Removing the lining
A stiff, transparent protective lining covers the sticky side of the patch, i.e. the side that will be placed against your skin. First remove the smaller piece of the transparent liner. Then peel off the larger piece. Try to avoid touching the adhesive and remember not to allow the patch to become folded so that the sticky surfaces come in contact with each other. Now apply the patch.





Applying the patch
With the palm of your hand press the sticky side of the patch firmly onto the spot you have chosen. Hold it there for about 10-20 seconds. Make sure that it sticks well, especially around the edges, but once the patch is in place do not pull at it to test that it is sticking properly.

When and how to remove the patch
The patches should be changed twice a week on the same two days of the week, e.g. Mondays and Thursdays. Choose two days which you are likely to remember.

You will find a table at the end of this leaflet for you to fill in to jog your memory. Tick the day of the week on which you are starting the treatment and keep this leaflet somewhere safe so that you can refer back to it if you need to.

When the time comes to change the patch, peel it off and fold it in half with the sticky side inside. Dispose of the patch carefully (see Section 5), making sure that it is kept out of the reach of children because it will still contain some medication. Stick a new patch onto a different area of skin.

What to do if a patch comes off
If a patch falls off it will not stick to your skin again. Use another patch on a different area of your skin (see **Where to apply the patch**). Make sure you choose a clean, dry, lotion-free area of the skin. No matter what day this happens, go back to changing the patch on the same days as usual.

Further useful information
- Bathing, swimming, showering or exercising should not affect the patch if it has been correctly applied. You may wear the patch under your swimming costume.
- Never apply a patch on a sweaty area or after a hot bath or shower. Wait until the skin is completely cool and dry.
- Do not remove the patch and try to put it somewhere else, it will not stick to your skin again. Instead apply a new patch in the usual way. Remember to apply your next patch at the normal time. If you have run out of patches, please contact your doctor straight away. (See also advice on 'What to do if a patch comes off'.)
- Sunbathing: always make sure your patch is covered by clothing.
- Using a sunbed: cover up the patch
- The drug in your patch is contained in the adhesive and not in a special reservoir.
- The drug in your patch is a gel which is colourless. This does not mean that the patch does not contain any medication.

If you use more Estraderm MX than you should
Remove the patch if you have used too much Estraderm MX. Symptoms of overdose are usually tenderness of the breasts and/or vaginal bleeding. Acute overdose is unlikely due to the way Estraderm is used (patch). If symptoms persist contact your doctor.

If you forgot to use Estraderm MX
If you forget to apply a patch, apply a new patch as soon as you remember. No matter what day that happens, go back to changing this patch on the same day as you usually do. There is an increased chance of breakthrough bleeding or spotting if there is a break in treatment. **Do not use a double dose to make up for the forgotten patch.**

If you stop using Estraderm MX
Stopping use of Estraderm MX may increase the risk of breakthrough bleeding or spotting. Talk to your doctor if this occurs. After a long break in treatment, consult your doctor before starting to use the patch again.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you need to have surgery
If you are going to have surgery, tell the surgeon that you are taking Estraderm MX. You may need to stop taking Estraderm MX about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking Estraderm MX again.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:
- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)

- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see Section 2.

Stop using Estraderm MX immediately and tell your doctor if you develop any of the following:
- Signs of a severe allergic reaction may include rash, itching, hives, breathlessness or difficulty in breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, low blood pressure, with or without mild generalised itching, skin reddening, swelling of the face, throat, lips, tongue, skin and swelling around the eyes
- Migraine or unusually severe headaches, or signs of stroke
- You become pregnant
- Signs of jaundice (yellowing of your skin or eyes).

<u>The side effects listed below have also been reported:</u>

Very common, may affect more than 1 in 10 people:
- Redness, pain and itching where the patch has been applied (signs of application site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, swelling, skin redness, inflammation, irritation, pain, tiny solid skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives, and blisters)
- Breast discomfort
- Breakthrough bleeding

Common, may affect up to 1 in 10 people:
- Headache
- Feeling sick or bloated, stomach ache

Uncommon, may affect up to 1 in 100 people:
- Breast cancer.

Rare, may affect up to 1 in 1,000 people:
- Unusual weight changes, fluid retention (swelling or accumulation of fluid in the lower legs or ankles), leg pain.
- Dizziness

Very rare, may affect up to 1 in 10,000 people:
- Blood clots, bruising, worsening varicose veins, raised blood pressure
- Abnormal liver function test results, jaundice
- Rash and itching over large areas of the skin. This sensitivity reaction may become severe if you carry on using the patches without talking to your doctor.
- Changes in the pigmentation in your skin (lightening or darkening of your skin colour)

Not known: frequency cannot be estimated from the available data
- Rapid changes in mood (e.g. depression, nervousness, etc.)
- Changes in sex drive
- Migraine
- Diarrhoea
- Vomiting
- Gallbladder disorder (tendency to form gallstones)
- Hair loss
- Darkening of the skin particularly on the face or abdomen (chloasma)

- Irregular heavy vaginal bleeding or constant spotting (possible signs of endometrial hyperplasia)
- Fibroids (benign growths in the uterus)
- Hives
- Back pain
- Menstrual cramps
- Tender, painful or swollen breasts
- Breast discharge
- Lumps in the breast (non cancerous)

If any of these apply to you and are severe, **tell your doctor**.

The following side effects have been reported with other HRTs:
- gallbladder disease
- changes in the composition of tear film
- various skin disorders:
  - discoloration of the skin especially of the face or neck known as 'pregnancy patches' (chloasma)
  - painful reddish skin nodules (erythema nodosum)
  - rash with target-shaped reddening or sores (erythema multiforme)
  - purple-colored spots that do not blanch on applying pressure (vascular purpura)
  - Dry eyes

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 via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Estraderm MX

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Store Estraderm MX in the original package, in order to protect from light. Once opened or once the protective pouch has been removed, the patch should be applied to the skin immediately.
- Do not use this medicine after the expiry date which is stated on the carton and patch after 'EXP'. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Estraderm MX contains
Estraderm MX 25 contains 0.75 mg oestradiol releasing about 25 micrograms of oestradiol a day.
Estraderm MX 50 contains 1.5 mg oestradiol releasing about 50 micrograms of oestradiol a day.
Estraderm MX 75 contains 2.25 mg oestradiol releasing about 75 micrograms of oestradiol a day.
Estraderm MX 100 contains 3.0 mg oestradiol releasing about 100 micrograms of oestradiol a day.

- The active substance is oestradiol (as hemihydrate).
- The other ingredients are acrylate, methacrylate, isopropyl palmitate, polyethylene terephthalate, ethylenevinylacetate copolymer.
- The backing film consists of ethylene vinyl acetate/polyester film laminate.

- The protective liner, which is removed before the patch is used, is a siliconized polyester film.

What Estraderm MX looks like and contents of the pack
Estraderm MX is a square-shaped, self-adhesive, transparent, transdermal patch for application to the skin surface. Each patch comprises an impermeable polyester backing film, an adhesive matrix containing oestradiol and an oversized protective liner which is removed prior to application of the patch to the skin.

Estraderm MX is available in four different strengths: 25, 50, 75 and 100 micrograms/ day.

Not all strengths may be marketed.

Estraderm MX is available in cartons of 8 patches (1 month pack) and 24 patches (3 months pack). Not all pack sizes may be marketed.

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and

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1083 HP Amsterdam,
Netherlands

This leaflet was last revised in 08/2025.

Fill this in to remind you when to change your patch. Please tick the box for the days of the week when you should change your patch.

- ❑ Monday + Thursday
- ❑ Tuesday + Friday
- ❑ Wednesday + Saturday
- ❑ Thursday + Sunday
- ❑ Friday + Monday
- ❑ Saturday + Tuesday
- ❑ Sunday + Wednesday

Other sources of information – If you need the information on this leaflet in an alternative format, such as large print, or Braille please ring 0800 198 5000.