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70 x 70 mm
Example for the
pre folded leaflet

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It is mandatory to use this die-cut.
Do not **REMOVE**, **CHANGE** or **ROTATE** anything on this die-cut!

Cutting	Format geschlossen / folded	Format offen / unfolded	Brüche / Folds
Text Area	70 x 70	413 x 346	9
Guides			
Dimensions			

Leaflet
valid from 15.05.2025

NOTE:
Use this DIE-CUT only for ESTRADOT

FRONT SIDE

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Estradot®

Estradot®

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Reading direction Pharmacode

70 mm | 70 mm | 70 mm | 65 mm | 413 mm

Package leaflet: Information for the user SZ27001LT02A

Estradot® 25 micrograms/24 hours transdermal patch
Estradot® 37.5 micrograms/24 hours transdermal patch
Estradot® 50 micrograms/24 hours transdermal patch
Estradot® 75 micrograms/24 hours transdermal patch
Estradot® 100 micrograms/24 hours transdermal patch

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

SANDOZ

1 What Estradot is and what it is used for

Estradot is a Hormone Replacement Therapy (HRT). It contains the female hormone oestrogen. Estradot is used in postmenopausal women with at least 12 months since their last natural period. Estradot comes as a patch that is applied to the skin.

Estradot is used for:

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

Prevention of osteoporosis (for Estradot 50, 75 and 100 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 Estradot to prevent osteoporosis after menopause.

2 What you need to know before you use Estradot

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

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

Do not use Estradot
if any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before using Estradot.

Do not use Estradot:
- 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** (hypersensitive) to estradiol or any of the other ingredients of Estradot (listed in section 6 Further information).

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

When to take special care with Estradot

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 Estradot. 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 an 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.

Stop using Estradot and see a doctor immediately

If you notice any of the following when using HRT:
- any of the conditions mentioned in the 'Do not use Estradot' 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: Estradot 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.

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

Unexpected bleeding
You will have a bleed once a month (so-called withdrawal bleed) while using Estradot in combination with a progestagen. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:
- carries on for more than the first 6 months;
- starts after you have been using Estradot for more than 6 months;
- carries on after you have stopped using Estradot;

see your doctor as soon as possible.

Breast cancer
Evidence shows that taking combined oestrogen-progestogen or oestrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. 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.

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

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/m^2);
- 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 using Estradot 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.

It is mandatory to use this die-cut.
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Cutting
Text Area
Guides
Dimensions

Format geschlossen / folded	Format offen / unfolded	Brüche / Folds
70 x 70	413 x 346	9

Leaflet
valid from 15.05.2025

NOTE:
Use this DIE-CUT only for ESTRADOT

REAR SIDE

346 mm

70 mm | 70 mm | 70 mm | 70 mm | 66 mm

Other medicines and Estradot
Some medicines may interfere with the effect of Estradot. 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, nelfinavir);
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*);
- Other **anti-infective medicines** (such as ketoconazole, erythromycin).

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 combinations regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir)) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using combined hormonal contraception (CHCs) containing ethinylestradiol. Estradot contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Estradot with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken 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 using Estradot, because this medicine can affect the results of some tests.

Pregnancy and breast-feeding
Estradot is for use in postmenopausal women only. If you become pregnant, stop using Estradot and contact your doctor. You should not use Estradot if you are pregnant or while you are breast-feeding.

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

3 How to use Estradot

Always use this medicine exactly as your doctor 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.

How long to use Estradot
It is important that you use the lowest possible effective dose and only as long as needed. From time to time, you should discuss with your doctor whether you still need the treatment.

When to start treatment
- **If you are currently not using any form of HRT** (patches or tablets), 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 Estradot 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), you should start to use Estradot on the day after you complete your previous cycle.

When to apply Estradot
- An Estradot patch should be replaced twice weekly (every 3 to 4 days). It is best to always replace it on the same two days of the week (e.g. Monday and Thursday). Your Estradot pack contains a calendar checklist on the back to help you remember your schedule. Mark the twice-a-week schedule that you plan to follow. Always change the patch on the two days of the week you have marked.
- Estradot should be worn continuously until it is time to replace it with a new patch.

Any adhesive that might remain on your skin can be easily rubbed off. Then place the new Estradot patch onto a different area of skin.

Women without a uterus
The Estradot patch is applied continuously without a break. Additional use of another type of hormone called progestogen is not required, unless you have a condition where the lining of the uterus also grows outside the uterus (*endometriosis*). Check the risks to be aware of with HRT in general in section 2, *When to take special care with Estradot*.

Women with a uterus
Your doctor should give you another hormone called progestogen in addition to Estradot to reduce the risk of cancer of the uterus. While Estradot is applied continuously without a break, the progestogen tablet should be taken for at least 12-14 days every month/28 day cycle. Check the risks to be aware of with HRT in general in section 2, *When to take special care with Estradot*.

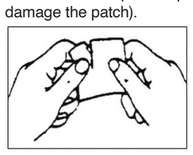
You may have some irregular bleeding or spotting during the first few months of treatment. If you have heavy bleeding or continue to have bleeding or spotting after a few months of treatment, tell your doctor so that the treatment can be re-evaluated if necessary (see section 2, *Unexpected bleeding*).

Where to apply Estradot
Apply the patch to the lower abdomen, below the waistline. Avoid the waistline itself, since clothing may cause the patch to rub off. Do not apply the patch to the breasts or any area near to the breasts.

When changing your patch, based on your twice-a-week schedule, apply your new patch to a different site. Do not apply a new patch to that same area for at least one week.

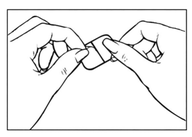
Before you apply Estradot, make sure that your skin is:
- clean, dry and cool,
- free of any powder, oil, moisturiser, or lotion,
- free of cuts and/or irritation.

How to apply Estradot
Each patch is individually sealed in a protective pouch. Tear open this pouch at the indentation and remove the patch (do not use scissors to open the pouch as this could damage the patch).

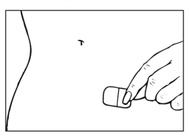


A stiff protective backing covers the sticky side of the patch. This backing must be removed before the patch is stuck to the skin. Apply the patch immediately after opening the pouch and removing the protective backing.

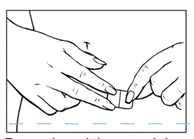
Hold the patch with the protective backing facing you. Peel off one side of the protective backing and discard it. Try to avoid touching the sticky side of the patch with your fingers.



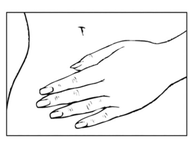
Holding the other half of the backing, apply the sticky side of the patch to a dry area of your lower abdomen. Press the sticky side to the skin and smooth down. Fold back the remaining side of the patch.



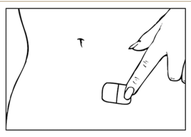
Grasp the straight edge of the protective backing and pull it off the patch.



Press the sticky remaining side of the patch to the skin and smooth down. Press the patch firmly in place with the palm of your hand for about 10 seconds.



Make sure that the patch sticks properly to your skin and go over the edges with your finger to ensure good contact between the patch and skin.



When changing the patch, peel it off, fold it in half with the sticky side inwards. Please see section 5, *How to store Estradot* for instructions on safe disposal of the patch. Do not flush used patches down the toilet.

Further useful information
Bathing, swimming, showering or exercising should not affect the patch if it has been correctly applied. If a patch falls off, e.g. during bathing or showering, shake it to remove the water. After careful drying and cooling down of the skin, reapply the same patch on a different area of the lower abdomen (see 'Where to apply Estradot').

If the patch does not stick completely to your skin, use a new patch. No matter what day this happens, go back to changing this patch on the same days as your original schedule.

When sunbathing or using a solarium, the patch should be covered. When swimming, the patch can be worn under your bathing suit.

If you need to have surgery
If you are going to have surgery, tell the surgeon that you are using Estradot. You may need to stop using Estradot 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 using Estradot again.

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

If you forget to use Estradot
If you forget to change the patch, change the patch as soon as you remember. No matter what day this happens, go back to changing the newly applied patch on the same days as your original schedule.
Do not use a double dose to make up for the forgotten patch.

If you stop using Estradot
Stopping use of Estradot 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.

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.

Some effects could be serious
These symptoms need immediate medical attention:
- Sudden chest pain;
- Pain in your chest that spreads to your arm or neck;
- Difficulty in breathing;
- Painful swelling and redness of the legs;
- Yellowing of the eyes and face, darkening of urine, itchy skin (*jaundice*);
- Unexpected vaginal bleeding or spotting (breakthrough bleeding) after using Estradot for some time, or after you stop treatment;
- Breast changes, including dimpling of the breast skin, changes in the nipple, lumps that you can see or feel (*breast cancer*);
- Painful menstrual periods;
- Unexplained migraine-like headaches.

Stop using Estradot and tell your doctor immediately if you get any of the effects mentioned above. Check the risks to be aware of with HRT in general in section 2, *When to take special care with Estradot*.

Other side effects
In addition, the following side effects have been reported with Estradot. **If any of these gets severe, tell your doctor or pharmacist.**

Very common, may affect more than 1 in 10 people:
Headache, skin reactions at the patch application site (including irritation, burning, rash, dryness, bleeding, bruising, inflammation, swelling, skin pigmentation, hives, and blisters), breast tension and pain, menstrual pains, menstrual disorder.

Common, may affect up to 1 in 10 people:
Depression, nervousness, mood changes, sleeplessness, nausea (feeling sick), indigestion, diarrhoea, abdominal pain, bloated feeling, acne, rash, dry skin, itching, breast enlargement, heavy menstrual periods, a white or yellowish discharge from the vagina, irregular vaginal bleeding, severe uterine contractions, inflammation of the vagina, abnormal growth of the womb lining (endometrial hyperplasia), pain (e.g. back pain, arms, legs, wrists, ankles), weakness, fluid retention (oedema) in the extremities (hands and feet), weight changes.

Uncommon, may affect up to 1 in 100 people:
Migraine, dizziness, increase in blood pressure, vomiting (being sick), skin discoloration, impaired liver function tests.

Rare, may affect up to 1 in 1,000 people:
Tingling or numbness of hand and feet, blood clot, gallstones, hair loss, muscular weakness, benign smooth muscle growth in uterus, cysts close to uterine tubes, polyps (small growths) in the uterine cervix (neck of the womb), changes in sexual desire, allergic reactions such as rash.

Very rare, may affect up to 1 in 10,000 people:
Hives, signs of serious allergic reaction (including difficulties to breath; swelling of face, tongue, throat or skin; dizziness and hives), decreased carbohydrate tolerance, involuntary movements which may affect the eyes, head and neck, contact lens discomfort, severe skin lesions, excessive hair growth.

Not known (cannot be estimated from the available data):
Breast cancer, liver function test abnormal, allergic skin inflammation, lumps in the breast (non-cancerous).

The following side effects have been reported with other HRTs:
- gallbladder disease
- 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).
- decline in memory or mental ability (possible *dementia*)

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 (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 Estradot

- Keep this medicine out of the sight and reach of children.
- Store Estradot in the original package in a cool, dry place. Once opened or once the protective pouch has been removed, the patch should be applied to the skin immediately.
- Do not refrigerate or freeze Estradot.
- 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.
- After removing a patch, fold it in half with the sticky side inwards and dispose of it safely out of the reach of children. Any used or unused transdermal patches should be disposed of in accordance with local requirements or returned to the pharmacy, preferably in the original packaging. Do not throw away any medicines via wastewater. 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 Estradot contains

Each 25 micrograms/24 hours patch contains 0.39 mg estradiol (as hemihydrate) and releases about 25 micrograms estradiol per 24 hours.
Each 37.5 micrograms/24 hours patch contains 0.585 mg estradiol (as hemihydrate) and releases about 37.5 micrograms estradiol per 24 hours.
Each 50 micrograms/24 hours patch contains 0.78 mg estradiol (as hemihydrate) and releases about 50 micrograms estradiol per 24 hours.
Each 75 micrograms/24 hours patch contains 1.17 mg estradiol (as hemihydrate) and releases about 75 micrograms estradiol per 24 hours.
Each 100 micrograms/24 hours patch contains 1.56 mg estradiol (as hemihydrate) and releases about 100 micrograms estradiol per 24 hours.

- The active substance is estradiol (as hemihydrate).
- The other ingredients in the adhesive layer of the patch are acrylic adhesive, silicone adhesive, oleyl alcohol, dipropylene glycol, povidone (E1201).
- The backing layer is an ethylene/vinyl acetate copolymer and vinylidene chloride/methyl acrylate copolymer laminate.
- The release liner (to be removed before application) is a fluoropolymer-coated polyester film.

What Estradot looks like and contents of the pack
Estradot 25 is a 2.5 cm^2 rectangular patch with rounded corners, comprising a pressure-sensitive adhesive layer containing estradiol, with a translucent polymeric backing on one side and a protective liner on the other.
Estradot 37.5 is a 3.75 cm^2 rectangular patch with rounded corners, comprising a pressure-sensitive adhesive layer containing estradiol, with a translucent polymeric backing on one side and a protective liner on the other.
Estradot 50 is a 5 cm^2 rectangular patch with rounded corners, comprising a pressure-sensitive adhesive layer containing estradiol, with a translucent polymeric backing on one side and a protective liner on the other.
Estradot 75 is a 7.5 cm^2 rectangular patch with rounded corners, comprising a pressure-sensitive adhesive layer containing estradiol, with a translucent polymeric backing on one side and a protective liner on the other.
Estradot 100 is a 10 cm^2 rectangular patch with rounded corners, comprising a pressure-sensitive adhesive layer containing estradiol, with a translucent polymeric backing on one side and a protective liner on the other.

Estradot is available in five different strengths: 25, 37.5, 50, 75 and 100 micrograms/24 hours. Not all strengths may be marketed in your country.

Estradot is available in cartons of 2, 8, 24 and 26 patches. Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Sandoz Limited
Maxis 1
Western Road
Bracknell
RG12 1RF
United Kingdom

Manufacturer:
Novartis Farmacéutica, S.A.
Gran Via de les Corts Catalanes, 764
08013 Barcelona
Spain

Novartis Pharma GmbH
Roonstrasse 25
D-90429 Nürnberg
Germany

Lek Pharmaceuticals d.d.
Verovškova ulica 57,
1526 Ljubljana
Slovenia
DUNS: 364704288

Hexal AG
Industriestraße 25
83607 Holzkirchen
Germany

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STO HOLZKIRCHEN

1.) Fill out by STO HOLZKIRCHEN
- **product name:** LF ESTRADOT TTS GB 413x346
- **mat.-no.:** 46397396
- **dimension:** 413 x 346 mm
- **pharma code:** 1063
- **packaging coordinator:** DJORDMI3
- **date of die cut creation:** 01.12.2025
- **packaging change no.:** ACR 400004795

2.) Technical check/plausibility check by STO HOLZKIRCHEN
- colour/count/legend available and correct
- font is outline
- correct material number
- pharmacode, reading direction, position
- dimension-accuracy/specification/key
- proper and consistent product name/trade name
- proper and consistent dosage in all places
- proper and consistent composition, active substance only
- preflight check - SAFS compliant

DO NOT REMOVE THIS PANEL !

Remarks:
- it is mandatory to use this SAFS compliant die-cut for artwork creation
- maximum 1 colours

This specification is SAFS compliant