

22nd October 2025

Dear Healthcare Professional,

Recent complaints for Estradot® transdermal patches (25, 50, 75 and 100 mcg/24 hrs)

Sandoz has been made aware of and received some complaints regarding Estradot (estradiol) transdermal patches 25, 50, 75 and 100 mcg/24 hrs. Sandoz has conducted an investigation following these complaints including retesting the batches concerned and can confirm that the **product meets all quality parameters and specifications**. No atypical trends were identified as part of post marketing surveillance in place at Sandoz.

Market complaints for transdermal patches are mainly received in two (2) primary areas: lack of adhesion and lack of efficacy (LOE). Adhesion issues generally might occur when the patch does not properly stick to the skin for the intended duration, potentially due to factors such as skin type, environmental conditions, or product formulation. This can lead to reduced drug delivery and user dissatisfaction. Similarly, complaints about LOE often arise when users perceive that the patch is not delivering the intended therapeutic effect, which can be the result of improper adhesion, individual variability in absorption, or other physiological factors. Both types of complaints are typical for this dosage form and are routinely monitored as part of post marketing surveillance.

Ten batches were assessed **with no discrepancies or deviations** identified in the manufacturing or packaging processes. Of the ten batches that have been the subject of recent complaints, B No 96622 has been of particular mention as a result. Based on the investigation, please be assured of product quality regardless of specific batch numbers. Sandoz will notify all impacted stakeholders if there is any update to product quality or other details.

Product description	Batch number	Complaint description	Outcome
Estradot 100 mcg / day	96622	Adhesion issue Lack of efficacy	No quality issue identified

Following the recent investigation Sandoz can confirm that **no complaint-related batches have exceeded the established global thresholds per defect type**.

This communication is:

- To reassure you that **no product-related issues have been identified** in any of the batches supplied to date and, in turn to reassure patients and reiterate the importance of the treatment, address perceived lack of efficacy, and if required, to speak to their clinician to discuss their treatment options if the product is not suitable and that there is no change to Estradot product profile in terms of safety and efficacy or batch specific concerns.
- To ensure quality use of medicines in light of the nature of the dosage form and no deviation from global trend of complaints regarding adhesion and lack of efficacy, and that although the matter remains under review, no product-related quality or regulatory actions are recommended at this time.
- Medsafe has monitored this investigation and has reviewed the information contained in this letter.

As always, we continue to encourage you to report to Sandoz all complaints received, which we routinely monitor as part of our post marketing surveillance; reporting details can be found below. Our Sandoz team will follow up on the complaints directly with the reporter and/or patient conditional to consent to follow up.

Given the absence of product-related issues, the reported complaints may be attributed to:

- **Application Technique** - Inconsistent skin preparation or placement.
- **Patient-Specific Variables** - Skin type, activity level, individual variability in absorption or use of lotions and the like.
- **Environmental Factors** - High humidity or temperature affecting adhesion or packaging.

Information for counselling patients on the use of Estradot transdermal patches

The product leaflet contained within each box of Estradot emphasises the importance of proper skin preparation and patch placement. Additionally, the leaflet also indicates that dose adjustments may be required and should be regularly discussed with the patient’s doctor.

The full product leaflet is attached below for your reference.

Estradot must be stored at or below 25°C. Do not freeze. Protect from light. The patches should not be stored once opened

and must be applied immediately upon removal from the protective sachet. Estradot patches must be kept out of the reach and sight of children.

Who should I contact if I have further questions about Estradot?

The Sandoz team is here to support you and your patients, you can contact the Sandoz team by calling **0800-SANDOZ (0800 726 369)** or by emailing Medical Information mi.new_zealand@sandoz.com

Further information

Before prescribing, please refer to the full Data Sheet and Consumer Medicine Information available on the Medsafe website <https://www.medsafe.govt.nz/profs/datasheet/e/estradotpatch.pdf> and <https://www.medsafe.govt.nz/consumers/cmi/e/estradot.pdf>

Pharmacovigilance reporting

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse event experienced with **Estradot Transdermal patch** must be reported by healthcare professionals and patients to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>.

This information can also be reported to Sandoz on **0800-SANDOZ (0800 726 369)** or adverse.event.nz@sandoz.com by email.

Sandoz is committed to ensuring that all our marketed products meet the highest standards. This letter is being distributed to all the pharmacists to ensure quality use of medicines and we sincerely thank you for communicating this to patients to ensure adequate support to patient queries and concerns. This notice is being issued after consultation with Medsafe.

Please forward this information to all relevant staff members in your organisation.

Yours faithfully,

DocuSigned by:
LIZ JOSHI
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Liz Joshi
Director, Scientific Affairs
Sandoz New Zealand Limited

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Estradot®

Estradot®

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SANDOZ
Manufactured by Noven Pharmaceuticals Inc., Miami, FL 33186

SANDOZ

How to Apply an Estradot® Patch

Where to apply the patch
Choose any area of skin on your abdomen below your waistline, where the patch will be covered by clothing.

You may wish to experiment with different locations when applying a new patch, to find ones that are most comfortable for you and where clothing will not rub on the patch.

- Do not stick the patch on:
- your breast: this may cause discomfort and unnecessary side effects
 - your waistline: clothing may rub the patch, causing it to fall off
 - skin that is very hairy or folded
 - skin that has had moisturiser, oils, lotions or powders on it: this will stop the patch from sticking
 - skin that has been scratched or is sore or itchy
 - skin that will be exposed to direct sunlight or a solarium

Preparing the skin

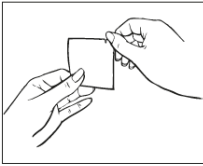
Apply the patch to freshly washed and dried skin that has no traces of moisturisers, oils, lotions or powders. Hot baths, steamy showers and even soaps with a high cream content can prevent the patch from sticking to your skin. You can use creams and lotions after you have applied the patch correctly.
If you wish to apply the patch after a bath or shower, wait 30 minutes to make sure your skin is completely cool and dry.
Once the patch has been applied, you can wear it during exercise or when bathing, swimming or showering. Contact with water shouldn't affect the patch if you have applied it properly.

Applying the patch

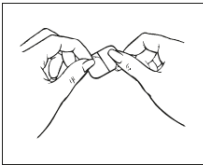
You should have a patch on all the time. Each patch is individually sealed in a protective pouch. Apply the patch immediately after opening the pouch.

Note: Only use one patch at a time. To reduce the possibility of skin irritation, do not put a new patch on the same area of skin as the one you've just used. Wait at least one week before using that area again.

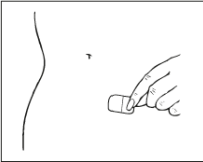
1. Tear open the protective pouch at the indentation and remove the patch (do not use scissors to open the pouch as this could damage the patch).



2. A stiff protective backing covers the sticky side of the patch. This backing must be removed before you stick the patch to the skin. 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.



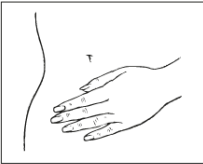
3. Holding the other half of the backing, apply the sticky side of the patch to a dry area of your abdomen. Press the sticky side to the skin and smooth down. Fold back the remaining side of the patch.



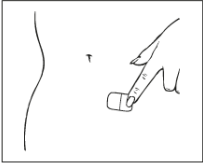
4. Grasp the straight edge of the protective backing and pull it off the patch.



5. Press the patch firmly in place with the palm of your hands for about 10 seconds.



6. Make sure that the patch has properly stuck to your skin. Go over the edges with your finger to ensure good contact around the patch.



Changing the patch

Change your patch twice weekly. It's easier to remember if you always do it on the same days (e.g. Monday morning and Thursday evening so that each patch is worn for 3½ days).

What to do if the patch falls off

If the patch falls off, you can reapply it to another area of skin. If the old patch does not stick properly, apply a new patch. No matter what day this happens, go back to changing the patch on the same days you always do (e.g. Mondays and Thursdays).

What to do if you forget to apply a patch

Apply a new patch as soon as you remember, and then go back to your usual schedule. If you have trouble remembering when to replace your patches, ask your pharmacist for some hints.

Removing and disposing of used patches

Peel off the patch, fold it in half with sticky sides together, and dispose of it out of the reach of children. You can easily rub off any glue that may remain on your skin.

More information

If you are not sure about the dosage of Estradot or how to use it, ask your doctor or pharmacist. Information on medicines is updated from time

to time and may have importance for you. For the most current information about this product, please ask your pharmacist or doctor for a copy of the latest Consumer Medicine Information (CMI) or go to www.sandoz.com.au.

Sponsor
SANDOZ PTY LTD
100 Pacific Highway, North Sydney
NSW 2060, AUSTRALIA
Tel 1800 726 369 (Australia),
0800 726 369 (New Zealand)
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