



19 September 2023

## **Medicine Supply Alert Notice**

### **Estradiol valerate/medroxyprogesterone acetate (Indivina<sup>®</sup>) 1mg/5mg tablets**

**Priority: Level 2\***

**Valid until: w/c 11<sup>th</sup> December 2023**

#### **Issue**

1. Estradiol valerate/medroxyprogesterone acetate (Indivina<sup>®</sup>) 1mg/5mg tablets are out of stock until w/c 11<sup>th</sup> December 2023.
2. Alternative continuous combined hormone replacement therapies (HRT) containing estradiol 1mg but a different progesterone component remain available and will be able to support increased demand.
3. Estradiol valerate/medroxyprogesterone acetate (Indivina<sup>®</sup>) 1mg/2.5mg tablets remain available but cannot support uplift in demand.
4. Where alternatives are not suitable, unlicensed supplies may be sourced, lead times vary.

#### **Advice and Actions**

5. Prescribers should:
  - not initiate patients on Indivina<sup>®</sup> 1mg/5mg tablets;
  - consider prescribing an alternative continuous combined HRT product containing estradiol 1mg but a different progestogen component to Indivina<sup>®</sup>, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose (see Additional Information below);
  - consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Additional Information below).

#### **Additional Information**

##### **Clinical Information**

6. The British Menopause Society (BMS) provides guidance from clinical experts on switching to alternative continuous combined HRT products. In this, BMS does acknowledge "The equivalence data included in this practical guide were based on a combination of pharmacokinetics, clinical trials and clinical experience. The dose equivalents included are subject to significant individual variations in absorption and metabolism." When switching patients to an alternative HRT product, prescribers will consider symptom control, side effect

profiles, breakthrough bleeds etc. The BMS also provides [advice on managing side effects of oestrogen and progestogens](#) where the options for progestogen side effects are: change the type of progestogen, reduce the dose if available, change the route of administration, alter the duration.

**Table 1:** Alternative oral continuous combined hormone replacement therapies

Product	Active ingredients
Femoston Conti® tablets	Estradiol 1mg/ Dydrogesterone 5mg
Kliovance tablets®	Estradiol 1mg/ Norethisterone 500mcg
Bijuve capsules®	Estradiol 1mg / Progesterone 100 mg

Links to further information:

- [British Menopause Society HRT preparations and equivalent alternatives](#)
- [HRT- Practical Prescribing](#)

Guidance on ordering and prescribing unlicensed imports

7. The following specialist importers have confirmed they can source unlicensed Indivina® 1mg/2.5mg tablets (please note there may be other companies that can also source supplies):
  - Alium
  - Target
8. Any decision to prescribe an unlicensed medicine must consider the relevant regulatory, professional and Board guidance and local governance procedures. Please see the links below for further information:
  - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
  - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
  - [Prescribing unlicensed medicines](#), General Medical Council (GMC)

**Specialist Pharmacy Service (SPS) website**

9. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.
10. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and

organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.

11. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
12. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

### **Enquiries**

13. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).