

Derbyshire Medicines Management, Prescribing and Guidelines DERBYSHIRE PRIMARY CARE FORMULARY

Chapter 7: Obstetrics, gynaecology, and urinary tract disorders

Updated: June 2023

The following prescribing guidelines are relevant to the obstetrics, gynaecology, and urinary tract disorders chapter and can be found here

- Continence appliance prescribing guideline community formulary
- Continence appliance prescribing guideline hospital formulary
- Continence product request form, top tips, NHSI urinary catheter tools
- Emergency Contraception
- Overactive Bladder- management
- Sayana Press- A guide for primary care

Relevant Resources:

- NHSI urinary catheter tool
- UHDB obstetric infections antibiotic guideline
- UHDB antenatal care guideline

7.2 Treatment of vaginal and vulval conditions

7.2.1 Preparations for vaginal and vulval changes

Estriol 0.1% (Ovestin) cream 15g Estriol 30 microg pessary Estradiol 10microg vaginal tablets 24

- 1. Ovestin cream (estriol 0.1%) and estriol <u>0.01%</u> cream with each applicator give the same dose due to different applicator sizes. Estriol 0.01% cream is expensive. Use Ovestin as more cost effective and smaller amount of cream for each dose.
- 2. Choice of local oestrogen preparation is based on patient preference to maintain compliance. Ovestin cream and Vagirux vaginal tablets come with applicator.

7.2.2 Vaginal and vulval infections

Clotrimazole pessary 500mg (1), cream 2% 20g

- 1. See <u>CKS</u> for management of vulvovaginal candidiasis- fluconazole 150mg as a single dose is 1st line. If oral treatment contraindicated or not suitable recommend clotrimazole 500mg pessary as a single dose. If there are vulval symptoms consider advising on use of a topical imidazole (clotrimazole 1% or 2% cream) in addition. Alternative treatment options include clotrimazole 10% cream, miconazole 2% cream, clotrimazole 200mg pessary.
- 2. Topical imidazoles preparations may damage latex condoms and diaphragms.

7.3 Contraceptives

Review patients on hormonal contraceptives at least **annually** for changes in risk factors, personal and family medical history. Full counselling, backed by the appropriate patient information leaflet/ resources should be provided. e.g. Family Planning Association (FPA) guides (require free registration), NHS website or sexwise website (by FPA)

NICE Clinical Guideline 30 Long-acting reversible contraception recommends:

• women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods;

- contraceptive service providers should be aware that:
 - All currently available LARC methods (intrauterine devices [IUDs], intrauterine system [IUS], injectable
 contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at
 1 year of use.
 - o IUDs, IUS and implants are more cost effective than the injectable contraceptives.
 - o Increasing the uptake of LARC methods will reduce the numbers of unintended pregnancies.

Other advice

- The Fraser Guidelines should be followed when prescribing contraception for women less than 16 years.
 The faculty of sexual and reproductive healthcare provides this and other useful information guidance www.fsrh.org.
- Interactions between hormonal contraception and other drugs- see FSRH guidance.
- Women taking a medicine of teratogenic potential- guidance on contraceptive methods and frequency of pregnancy testing. See MHRA March 2019; guidance; FSRH statement.

7.3.1 Combined hormonal contraceptives (CHC)

Below are preferred cost-effective choices for oral CHC. Health care professionals should support women to make informed decisions about choosing and using CHC, ensuring that they are informed about contraceptive effectiveness (and how this compares to other contraceptive methods) as well as potential risks and benefits.

Ethinyloestradiol 20 micrograms				
Brand Name	Contraceptive formulation	Use	Comments and alternative equivalent brands for information	
Bimizza	Ethinyloestradiol 20microg desogestrel 150microg	1 st line option	Same formulation as Gedarel 20/150, Mercilon	
Millinette 20/75	Ethinyloestradiol 20microg gestodene 75microg	2 nd line option	Same formulation as Femodette, Sunya	
	Ethinyloestradiol 30 micrograms			
Levest	Ethinyloestradiol 30microg levonorgestrel 150microg	1 st line option in new users	 Review patients at 35 years of age Useful if require a more progestogen dominant pil Same formulation as Rigevidon, Ovranette, Microgynon 30, Maexeni, Elevin, Ambelina 	
		or 2 nd line	If oestrogenic side-effects with Brevinor	
Cimizt	Ethinyloestradiol 30microg desogestrel 150microg	2 nd line option	Same formulation as Gedarel 30/150, Marvelon	
Millinette 30/75	Ethinyloestradiol 30microg gestodene 75microg	3 rd line option	Same formulation as Katya, Femodene	
Ethinyloestradiol 35micrograms				
Brevinor	Ethinyloestradiol 35microg norethisterone 500microg	First line option also useful	 In new users Oestrogen dominant pill If suffering progestogenic effects of Rigevidon, 	
	ŭ	2 nd line	Microgynon 30, Ovranette	

N.B. products are selected by cost-effectiveness as per MIMS June 2023

- 1. Appropriate for women up to 50 years of age if no risk factors for CVD, provided a CHC is otherwise suitable. Caution re: risk of VTE with BMI ≥30 (contraindicated with BMI ≥35). Avoid in women aged over 50. Avoid in smokers aged 35 years and over.
- 2. There is an increased risk of venous thromboembolic disease in users of combined hormonal contraceptives particularly during the first year and possibly after restarting combined hormonal contraceptives following a break of four weeks or more. This risk is considerably smaller than that Page 2 of 9

^{*}New brands of oral contraceptives are constantly being launched and prescribers may find this information helpful in selecting formulary equivalents

- associated with pregnancy (about 60 cases of venous thromboembolic disease per 100,000 pregnancies). The MHRA in <u>February 2014</u> confirmed the small VTE risk of CHCs and recommended that prescribers consider risk factors and remain vigilant for signs and symptoms.
- 3. The MHRA in <u>March 2014</u> advised **St John's Wort interacts with hormonal contraceptives** including implants. This interaction reduces the effectiveness of these contraceptives and increases the risk of unplanned pregnancy
- 4. CHCs containing both oestrogen and progestogen are the most effective. A low hormone content pill should be tried initially and the patient maintained on a preparation with the lowest oestrogen and progestogen content consistent with good cycle control and minimal side effects. Preparations containing the older progestogens levonorgestrel and norethisterone are to be preferred.
- 5. **Phased preparations** are available but they are more complicated to use. They may help to improve cycle control with a lower dose increase in some women, where this is inadequate with a recommended (monophasic) preparation above. These are reserved for women who either do not have withdrawal bleeding or who have breakthrough bleeding with monophasic.
- 6. Ethinylestradiol 30microg/drospirenone 3mg (Yacella is preferred choice), Lucette, Yasmin are reserved options after above formulary choices. However, the patient should have tried at least two other CHC's including a third generation one i.e. containing either Gestodene or Desogestrel.
- 7. Evra patch is **GREY** 2nd line to oral formulary CHC. Reserved for women who have demonstrated or are deemed to be at substantial risk of poor compliance with oral CHC. It is significantly more expensive than oral CHC.
- 8. Ethinylestradiol+ etonogestrel vaginal ring is **GREEN after consultant/specialist initiation**. Brands include NuvaRing and SyreniRing.
- 9. Be aware that oestrogen-containing hormonal contraceptives and hormone replacement therapy can impair the effectiveness of lamotrigine. (NICE NG217)
- 10. CHC in patients taking hepatic enzyme inducing drugs- see SPS advice.
 - For women taking enzyme inducers e.g. rifampicin, the preferred method of contraception would be an intrauterine device or an injectable such as medroxyprogesterone.
 - For women taking less potent enzyme inducers e.g. carbamazepine or phenytoin there is some scope to consider other methods instead.
 - For short term use (<2 months) of less potent enzyme inducers, a minimum of 30 micrograms ethinylestradiol pill continuously or tricycle with a shortened 3 or 4 day pill-free interval can be used for the duration of treatment and for a further 28 days (with additional precautions such as the use of condoms).
 - For longer term use of less potent enzyme inducers, a daily dose of at least 50 micrograms of oestrogen should be used (to a maximum of 70 micrograms). This is taken continuously or as a tricycling regimen with a PFI of 4 days for the duration of treatment and a further 28 days.

Tailored regimens

Traditional cyclical pill regimens were designed to induce a bleed each month, however the bleed is due to the withdrawal of hormones rather than physiological menstruation. Women should be given information about both standard and tailored CHC regimens. Tailored regimens may be considered in women with e.g. troublesome adverse effects such as painful heavy periods and headache during pill free interval. FSRH suggests using one of the following tailored regimens: (note this is off-licensed and only applies to monophasic 21-day COC)

Type of tailored regimen	Period of CHC use	HFI
Shortened hormone-free interval (HFI)	21 days (21 active pills or 1 ring, or 3 patches)	4 days
Extended use (tricycling)	9 weeks (3 x 21 active pills or 3 rings, or 9 patches used consecutively)	4 or 7 days
Flexible extended use	Continuous use (>21 days) of active pills, patches or rings until breakthrough bleeding occurs for 3-4 days	4 days
Continuous use	Continuous use of active pills, patches or rings	None

Reference: FSRH Clinical Guideline: Combined Hormonal Contraception (January 2019, amended November 2020) https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/

7.3.2 Progestogen only contraceptives:

Oral progestogen only contraceptives

Brand Name	Progestogen/ strength	Comments and alternative equivalent brands* for information	
Noriday	Norethisterone 350microg	follow the missed pill rules if the pill is taken more than 3 hours late	
Norgeston	Levonorgestrel 30microg	follow the missed pill rules if the pill is taken more than 3 hours late	
Desogestrel	Desogestrel 75microg	 follow the missed pill rules if the pill is taken more than 12h late cost-effective to prescribe generically. some generics may contain ingredients unsuitable for soya or nut allergy sufferers - these patients should check with the pharmacist when these products are dispensed for allergens. Brands* include Zelleta, Feanolla, Cerelle Brands costing over £5 e.g. Cerazette are classified Do Not Prescribe (DNP). 	

N.B. products are selected by cost-effectiveness as per MIMS June 2023

1. Progestogen-only contraceptive pills (Hana and Lovima- desogestrel 75 microg) have been made available to be purchased over the counter from pharmacies without prescription, increasing choice for women in the ways in which they can access contraception. See MHRA.

Parenteral progestogen only contraceptives

Brand Name	Progestogen/ strength	notes
Depo-Provera	Medroxyprogesterone acetate 150mg/ml	Deep intramuscular injection given at 12 week interval See notes below on medroxyprogesterone
Noristerat	Norethisterone 200mg	Deep intramuscular injection given at 8 weeks interval
Sayana Press	Medroxyprogesterone acetate 104mg/0.65ml	Subcutaneous injection for patient self-administration at 13-week interval. See local <u>quideline</u> See notes below on medroxyprogesterone
Nexplanon	Etonogestrel 68mg	Subdermal implant. Remove within 3 years

- 1. Etonogestrel (Nexplanon)- The MHRA Drug Safety Update (<u>February 2020</u>) provides amended advice on the insertion site for etonogestrel (Nexplanon) contraceptive implants following concerns regarding reports of neurovascular injury and implants migrating to the vasculature (including the pulmonary artery).
- 2. Medroxyprogesterone acetate- full counselling, backed by manufacturer's approved leaflet is required before administration.
 - In women aged under 18 years progestogen-only injectable contraception can be used after consideration of alternative methods.
 - Women using depot medroxyprogesterone acetate (DMPA) who wish to continue use should be reviewed every 2 years to assess individual situations, and to discuss the benefits and potential risks.
 - In women with risk factors for osteoporosis, a method of contraception other than medroxyprogesterone acetate should be considered.

^{*}New brands of oral contraceptives are constantly being launched and prescribers may find this information helpful in selecting formulary equivalents

Intra-uterine progestogen only system

The health professional should be fully trained in the technique and should provide full counselling backed by the patient information leaflet.

	Levosert	Mirena	Kyleena	Jaydess
Total LNG content (mg)	52mg	52 mg	19.5 mg	13.5 mg
Frame size (W x H)	32 x 32 mm	32 x 32 mm	28 x 30 mm	28 x 30 mm
Inserter	Levosert inserter	r One handed Evolnserter™		er™
Insertion tube diameter	4.8mm	4.4mm	3.8mm	3.8mm
Licensed duration of use for contraception	6 years*	8 years*	5 years	3 years
Licensed for endometrial protection?	No	Yes	No	No
Licensed for heavy menstrual bleeding?	Yes	Yes	No	No
Unit cost (£)	66	88	76	69.22
Cost per year over period of licensed use (£/year)	11	11	15.2	23.07

Information on Intra-Uterine system taken from Faculty of Sexual and Reproductive Healthcare (FSRH)

7.3.3 Spermicidal contraceptives

No recommendations for this section

7.3.4 Contraceptive devices

No recommendations for this section.

Seek advice from Sexual Health Services https://www.yoursexualhealthmatters.org.uk/

The most effective intra-uterine devices have at least 380mm² of copper and have banded copper on the arms

7.3.5 Emergency contraception (EC)

All women seeking emergency contraception should be advised that a copper IUD is more effective than emergency hormone contraception (EHC). "A copper IUD (or advice on how to obtain one) should be offered to all women attending for emergency contraception, even if they present within 72 hours of unprotected sexual intercourse" (FSRH 2017) See local Emergency Contraception guideline.

Women should be advised that if they have already ovulated there is no evidence that hormonal emergency contraception has any effect.

Levonorgestrel 1.5mg (Emerres /Upostelle) Ulipristal acetate 30mg (EllaOne)

- 1. Do not prescribe as 'Levonelle One Step' as this is the OTC preparation and more expensive.
- 2. Women using liver enzyme-inducing drugs should be advised that an IUD is the preferred option for Emergency Contraception (Grade A). Women who are using liver enzyme-inducing drugs who are given 1.5 mg tablets of levonorgestrel should be advised to take a total of 3 mg (two tablets) as a single dose, as soon as possible and within 72 hours of unprotected sexual intercourse. This use is outside the product licence. MHRA September 2016
- 3. For missed pills levonorgestrel is the preferred option.

Quick starting contraception includes:

- Starting contraception at a time other than the beginning of the menstrual cycle, but it is reasonably certain that there is **no risk of pregnancy**.
- Starting contraception at a time other than the beginning of the menstrual cycle and there is a potential risk of very early pregnancy from recent unprotected sexual intercourse (but it is too early to exclude pregnancy using a high- sensitivity pregnancy test). Quick starting in this situation is appropriate if a woman considers it likely that she will continue to be at risk of pregnancy or if she wishes to avoid delaying commencement of contraception.

^{*}Recommended duration of use for contraception (individuals age ≥45 years at time of insertion) until age 55

After oral emergency contraception, further episodes of unprotected intercourse in the same cycle put women at risk of pregnancy therefore quick starting method is advised.

- After **levonorgestrel** EC administration, combined oral contraceptives, progesterone only pills, progestogen-only implant (and depot medroxyprogesterone acetate) can be quick started **immediately**.
- After **ulipristal acetate** EC administration, they should **wait 5 days** before quick starting suitable hormonal contraception**.

Number of days for abstinence or barrier methods after oral emergency contraception dose:

Type of HC	Quick start after ulipristal after 5 day delay	Quick start after levonorgestrel
Combined oral contraceptive pill (except Qlaira®)	5 day delay+7 days	+7 days
Qlaira® - combined oral contraceptive pill	5 day delay +9 days	+9 days
Combined vaginal ring/ transdermal patch	5 day delay +7 days	+7 days
Progestogen-only pill	5 day delay +2 days	+2 days
Progestogen-only implant or injectable	5 day delay +7 days	+7 days

FSRH Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

- LNG-EC may be offered, with immediate restart of CHC and use of condoms for 7 days
- if UPA-EC is preferred, it may be offered, now with **immediate restart of CHC and use of condoms** for **7 days**.

7.4 Drugs for genito-urinary disorders

7.4.1 Drugs for urinary retention

Doxazosin tabs 1mg, 2mg, 4mg First line
Tamsulosin m/r caps 400microg Second line

Tamsulosin+ dutasteride caps 400/ 500microg if combination with 5-alpha reductase inhibitor required

- 1. Prescribe tamsulosin m/r capsules rather than the m/r tablets, as these are more cost effective.
- 2. Doxazosin MR preparation has been classified as **Do Not Prescribe (DNP)** as more costly than the immediate release preparation with only marginal benefits in relation to side effects.
- 3. The combination product tamsulosin 400microg and solifenacin 6mg (Vesomni) has been classified as **Do Not Prescribe (DNP)**. Usual dose for solifenacin 5-10mg, Vesomni contains 6mg of solifenacin, swap from individual components not easily achieved. Other combinations of individual products are cheaper than Vesomni
- 4. The combination product Combodart (tamsulosin 400microg and dutasteride 500microg) has been classified as **Do Not Prescribe (DNP)** as significantly more expensive than the individual components or the generic combination capsule.

7.4.2 Drugs for urinary frequency, enuresis, and incontinence

See <u>Primary care management of overactive bladder</u>. In urge incontinence, antimuscarinic drugs can reduce contractions and increase bladder capacity.

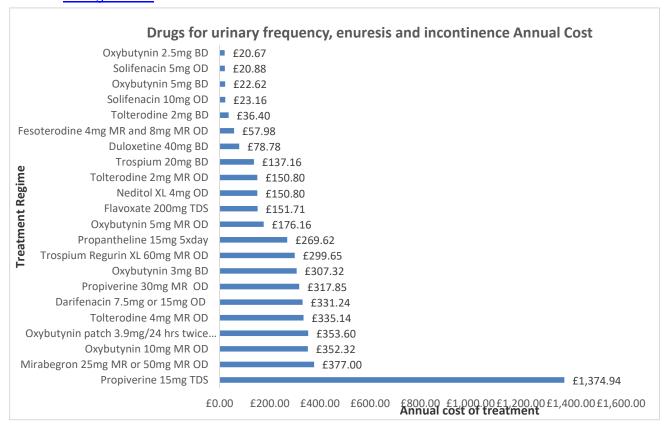
Oxybutynin tabs 2.5mg, 5mg 1st line. Important to titrate the dose slowly

Solifenacin tabs 5mg, 10mg 1st line Tolterodine tabs 2mg 2nd line

- 1. Stress incontinence is generally managed by non-drug methods such as pelvic floor exercises and bladder training.
- 2. Prescribe anticholinergic drugs with caution in older or frail people or people with complex multimorbidities. See relevant resources on anticholinergic drugs / burden, mARS & ACB scale.

^{**} If EC is considered to be required in the specific situation in which an established CHC user restarts CHC after a hormone-free interval and then misses 2-7 pills in the first week of pill-taking (or makes an equivalent error with combined patch or ring use): See FSRH CEU statement

- 3. NICE NG123 Urinary incontinence and pelvic organ prolapse in women: management advises not to offer oxybutynin immediate release to older women who may be at higher risk of a sudden deterioration in their physical or mental health.
- 4. Choice of third line agent should take into account possible advantages of specific agents and cost- see also local guidance.



(Annual cost of treatment (DT Prices accessed June 2023)

5. Mirabegron (NICE TA290) is **Grey** - another third line choice after a trial of solifenacin and oxybutynin. MHRA Drug Safety Update in October 2015 issued a safety warning stating mirabegron is contraindicated in patients with severe uncontrolled hypertension (systolic blood pressure ≥180 mm Hg or diastolic blood pressure ≥110 mm Hg, or both). Blood pressure should be measured before starting treatment and monitored regularly during treatment, especially in patients with hypertension.

7.4.3 Drugs used in urological pain

No drug is recommended for this section.

For treatments of minor self-limiting conditions such as mild cystitis patients are encouraged to self-care. Treatments are available to purchase over-the-counter.

7.4.4 Bladder instillations and urological surgery

No drug is recommended for this section.

7.4.5 Drugs for erectile dysfunction

Sildenafil tabs 25, 50, 100mg

- Sildenafil is the preferred first line treatment option for erectile dysfunction. From 1st August 2014
 restrictions on the prescribing of **generic** sildenafil for erectile dysfunction (ED) have been lifted
 following <u>new legislation</u> meaning that generically written prescriptions for sildenafil **no longer require**the annotation "SLS".
- 2. SLS regulations still apply to Viagra brand and all other PDE5 inhibitors (branded and generic) for the treatment of ED (see note 6 below). ALL male patients are entitled to NHS treatment for erectile

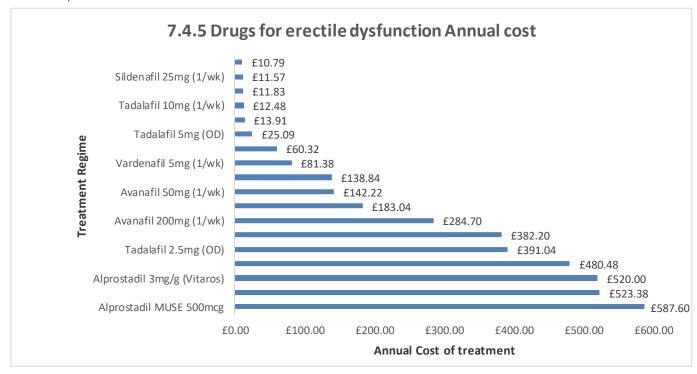
dysfunction with generic sildenafil but only those with certain conditions are entitled to NHS treatment with any of the other treatments including tadalafil.

- 3. The criteria for NHS prescribing (SLS) are:
 - diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, or spinal cord injury
 - · are receiving dialysis for renal failure;
 - have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate), or kidney transplant;
 - were receiving Caverject®, MUSE®, Viridal®, Uprima®, Erecnos®, Viagra®, or Cialis® for erectile dysfunction, at the expense of the NHS, on 14 September 1998

The prescription must be endorsed 'SLS'

In addition, specialist centres can prescribe PDE-5 inhibitors on the NHS if the man is 'suffering severe distress as a result of impotence' that causes:

- Significant disruption to normal social and occupational activities
- A marked effect on mood, behaviour, social, and environmental awareness
- A marked effect on interpersonal relationships.
- 4. 'Viagra Connect' (sildenafil 50 mg film-coated tablets) has been reclassified from a prescription only medicine (POM) to a Pharmacy medicine (P) in November 2017 (see MHRA) due to its favourable and well known safety profile. It is indicated for adult men over the age of 18 years with ED, and will be available for suitable patients to purchase from pharmacies without having to consult a doctor. It will not be sold to those with severe cardiovascular disorders; at high cardiovascular risk; liver failure; severe kidney failure; or taking certain interacting medicines. Patients wish to use brand Viagra who do not fit SLS criteria may be advised to purchase OTC.
- 5. Vardenafil, avanafil and tadalafil are classified as **GREY** and are considered to be equally effective; therefore, choice should be based on cost:



Annual cost of treatment (prices accessed June 2023)

6. Tadalafil 5mg **once daily** preparation for erectile dysfunction (for patients meeting SLS criteria and therefore eligible for NHS prescription) is **GREY** - an option and cost effective when a PDE5 inhibitor requirement for a patient is greater than 8 doses per month.

Tadalafil 2.5mg **once daily** preparation for erectile dysfunction is **DNP** significantly more expensive compared to other available treatment.

- 7. Men should have used six doses of PDE-5 inhibitor at maximum dose (with sexual stimulation) before being classified as non-responder. Consider referring to a specialist in patients who fail to respond to the maximum dose of at least two different PDE-5 inhibitor.
- 8. The recommended quantity to prescribe is one tablet/appliance a week for most patients, as excessive prescribing could lead to unlicensed, unauthorised and possible dangerous use of these treatments (HSC 1999/148). Prescribe suitable quantity for individual clinical circumstances.
- 9. Alprostadil (Caverject, Viridal Duo, Vitaros) is **GREY after specialist initiation**. Alprostadil cream (Vitaros) is recommended for those patients who have failed phosphodiesterase inhibitor treatment and who are unwilling to use alprostadil/invicorp injections.
- 10. Vacuum pumps are a 2nd line option following treatment with PDE5 inhibitors, after assessment and recommendation by a specialist. JAPC has classified the vacuum pumps as RED for new patients requiring assessment of the condition and training on use of the device for erectile dysfunction as per SLS criteria. See out of area guidance for request from outside of Derbyshire.
- 11. The penile constrictor rings (for use with the vacuum pump) have been classified as GREEN after specialist initiation. Constrictor rings vary in price and ring size (£4-£7) and last for approximately 8 uses.
- 12. Sildenafil has been classified as **RED** for systemic sclerosis (digital ulcers).

7.4.6 Drugs for Premature Ejaculation (PE)

The Derbyshire JAPC has classified dapoxetine as **Do Not Prescribe (DNP)** (not recommended or commissioned) for the treatment of premature ejaculation. For management of PE see European association of urology <u>guideline</u>. Off-label use of SSRI (e.g. paroxetine, sertraline, fluoxetine) is the treatment of choice. other treatment options include topical anaesthetic agents e.g. lidocaine/prilocaine.