Somerset Integrated Care System

NHS Somerset

Family and Sexual Health update

-Menopause

-Safe Prescribing in Pregnancy

Sam Morris
Pharmacist Medicines Manager

May 2023

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Menopause

Menopause and Hormone Replacement Therapy - NHS Somerset

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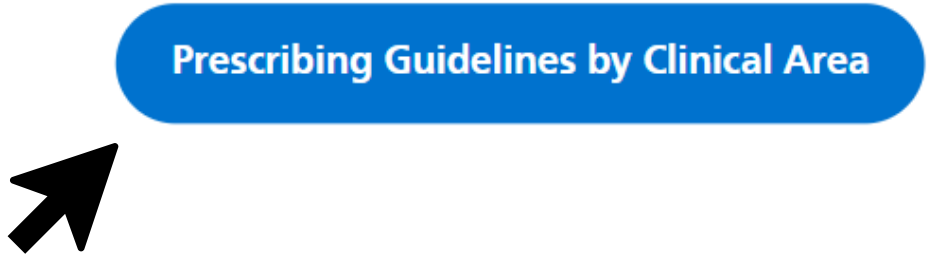
Website resources

- Prescribing and Medicines Management - NHS Somerset



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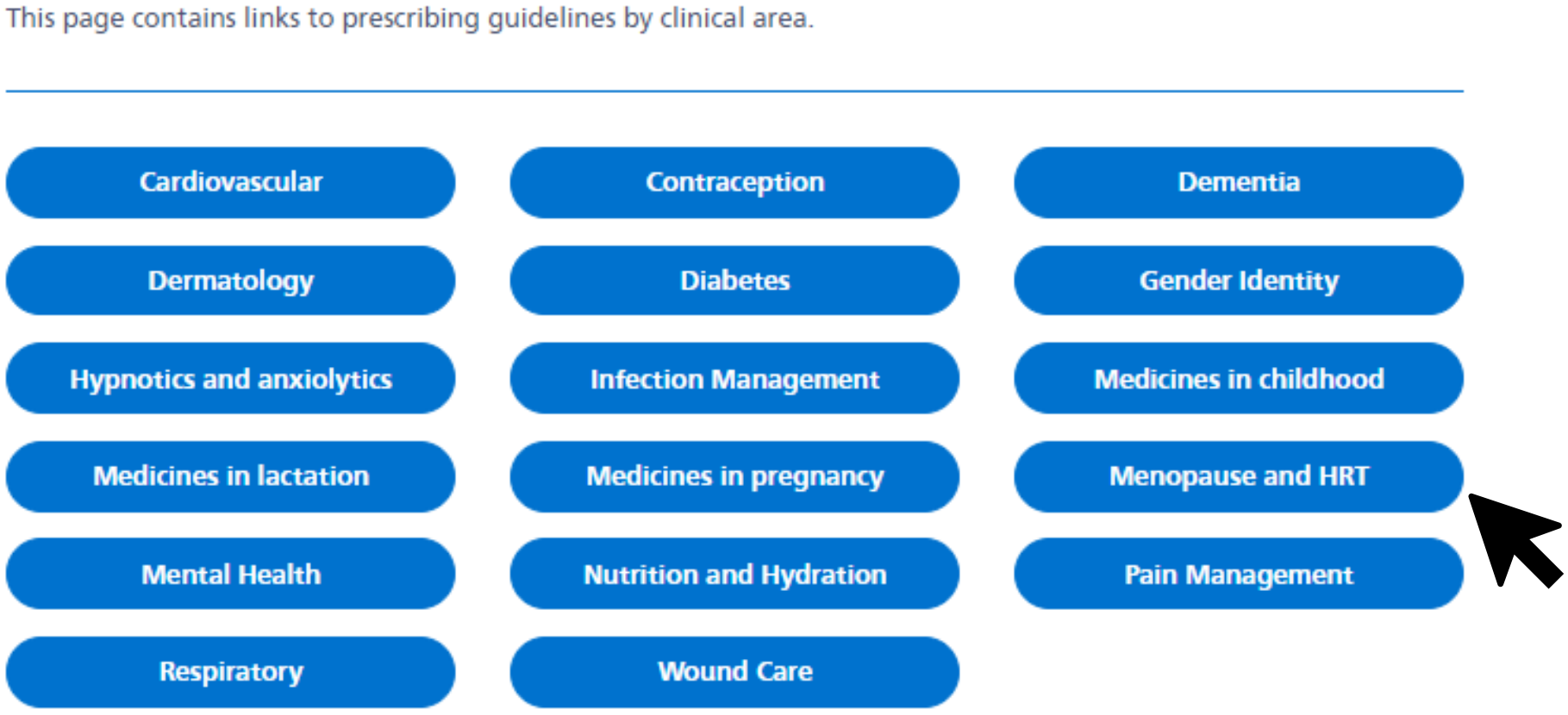

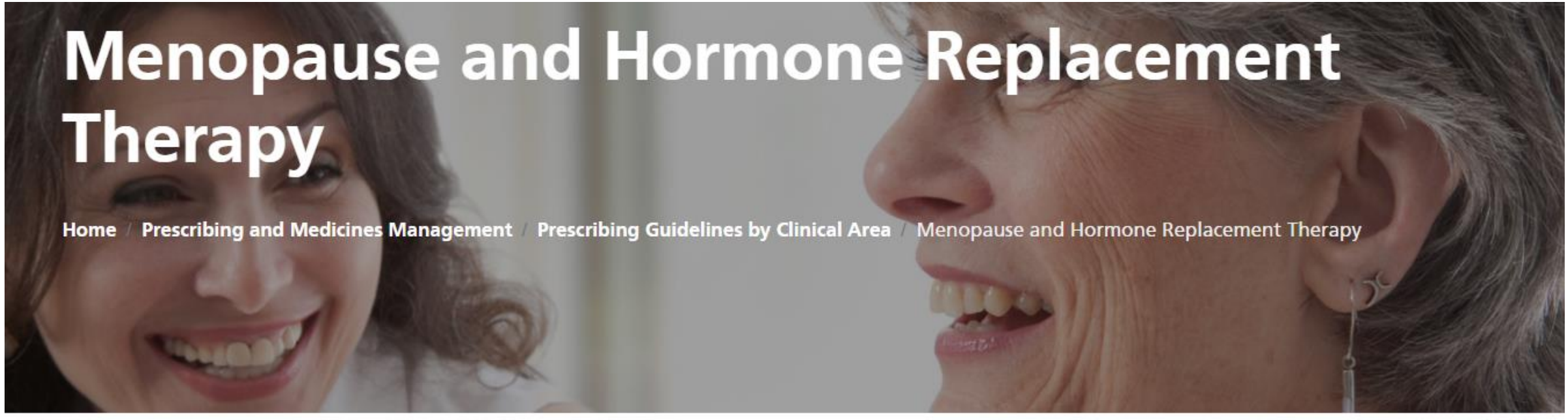

Menopause and Hormone Replacement Therapy

This formulary page covers diagnosis and management of menopause following NICE guideline **[NG23] Menopause: diagnosis and management**.

The guidance aims to support in the diagnosis and management of menopause including people with premature ovarian insufficiency to support GPs so they can optimise their patient's treatment choices with them.

Please expand the topics below to see more detail. There are several resources also under Resources below, some of these will be useful to use with patients, but they may also support you in CPD. The HRT formulary is linked, however specific detail is shared as treatment pathways in each of the further pages under transdermal, oral or topical options.

Transdermal HRT **Oral HRT** **Topical HRT**

HRT Formulary **Testosterone**

In this section

- Cardiovascular System
- Gender Identity
- Contraception
- Dementia
- Dermatology
- Diabetes
- Hypnotics and Anxiolytics
- Menopause and Hormone Replacement Therapy

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HRT Formulary Options

For formulary information on testosterone, see below accordion on this page

See the **SPS supply availability page** for current stocks

The British Menopause Society (BMS) have provided an **HRT preparations and equivalent alternatives** document which may be useful when switching preparations or switching to manage out of stock situations.

- Resources +
- Long Term Benefits and Risks of HRT +
- Breast Cancer or High Risk of Breast Cancer +
- Breastfeeding and Menopause +
- Contraception and Menopause +
- Diagnosis of Menopause +
- Diagnosing Premature Ovarian Insufficiency +
- Managing Premature Ovarian Insufficiency +
- Gender Language and Definitions +
- HRT Options Chart +
- Osteoporosis +
- Psychological Symptoms and Mental Health in Menopause +
- Starting and Stopping HRT +
- Summary of HRT Risks +
- Testosterone +
- Unscheduled and Vaginal Bleeding Problems +
- Urogenital Atrophy +
- Vasomotor symptoms +
- Working with Menopause +

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The Menopause

The menopause usually occurs between 45 and 55 years of age. The average age in the UK is 51. It is defined as when a woman has had no periods for one year or more. Before then a woman will experience ‘early peri-menopause’ and ‘late peri-menopause’.

Early peri-menopause Women initially experience a change in menstrual cycle pattern when periods become infrequent and the cycles become slightly longer, e.g. 6-7 weeks apart. This phase is called the ‘early peri-menopause’. The average age it occurs is 47 and it is when women may start experiencing menopausal symptoms.

Late peri-menopause Subsequently, many women experience worsening of their menopausal symptoms. Menstrual cycles become less frequent, with periods a few months apart. This is called the ‘late peri-menopause’ and the average age it occurs is 49.

17-BMS-TfC-What-is-the-menopause-NOV2022-A.pdf (thebms.org.uk)

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Perimenopause Symptoms

The most common symptoms are hot flushes and night sweats (vasomotor symptoms), experienced by 70-80% of women.

Other symptoms include disturbed sleep and insomnia, low energy levels, low mood, anxiety, low libido and low sexual drive, impaired memory and concentration, a sensation of ‘brain fog’, joint aches, headaches, palpitations and vaginal dryness and urinary symptoms.

Menopausal symptoms last on average for more than 7 years and it is estimated that more than a third of women experience long-term menopausal symptoms which may continue for a number of years beyond that.

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Diagnosis

Diagnose the following without laboratory tests in otherwise healthy women or people assigned female at birth (AFAB), aged over 45 years with menopausal symptoms:

- -perimenopause based on vasomotor symptoms and irregular periods
- -menopause in women and people AFAB who have not had a period for at least 12 months and are not using hormonal contraception
- -menopause based on symptoms in women and people AFAB without a uterus.

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Diagnosis

Consider using a FSH test to diagnose menopause only:

- -in women aged 40 to 45 years with menopausal symptoms, including a change in their menstrual cycle
- -in women aged under 40 years in whom menopause is suspected

Premature ovarian insufficiency

Diagnose premature ovarian insufficiency in women aged under 40 years based on:

- menopausal symptoms, including no or infrequent periods (taking into account whether the woman has a uterus) **and**
- elevated FSH levels on 2 blood samples taken 4–6 weeks apart.
- If there is doubt about the diagnosis of premature ovarian insufficiency, refer the woman to a specialist with expertise in menopause or reproductive medicine.
- Do **not** diagnose premature ovarian insufficiency on the basis of a single blood test.
- Do **not** routinely use anti-Müllerian hormone testing to diagnose premature ovarian insufficiency.

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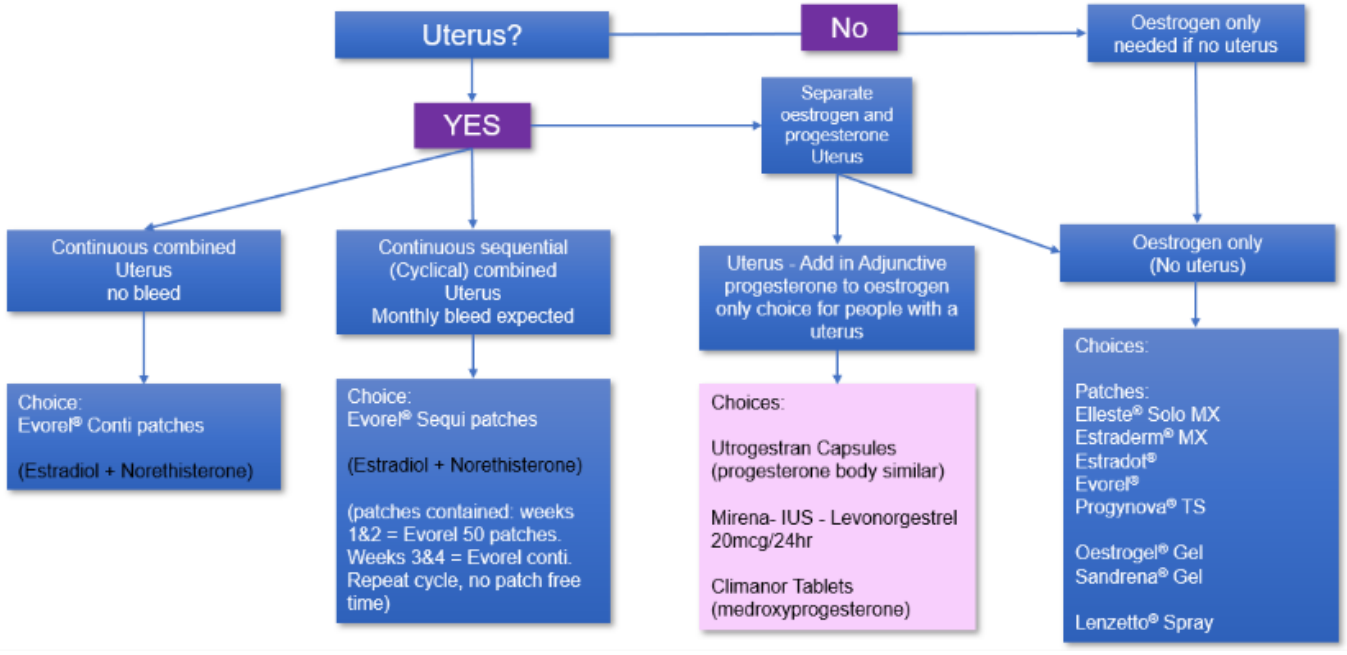
Treatment options

Transdermal HRT | Oral HRT | Topical HRT

HRT Formulary | Testosterone

HRT formulary - Transdermal options - First choice



Effectiveness of transdermal oestradiol and natural micronised progesterone for menopausal symptoms (nhssomerset.nhs.uk)

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HRT pre-payment certificates from April

Medicines covered by the HRT PPC | NHSBSA

- The HRT PPC does not cover all HRT medicines. A list of eligible HRT medicines can be found on the **NHSBSA** website.
- **Please ensure that two separate prescription forms are issued for multiple items so HRT items are on their own form.**
- If prescriptions have mixed HRT and another item on the same form but the patient only has a HRT PPC then the pharmacy may refuse to dispense some or all of the items and refer patient back to the prescriber, which would obviously cause inconvenience and additional workload to all.
- EMIS will be updating the system to automatically pull HRT items into a separate form, until that happens, **please continue to do this manually.**

Not clonidine, antidepressants or testosterone.
A full pre-pay certificate may be more appropriate for people on >3 items in 3 months, or >11 in 12

...

- Do not presume low mood is depression in perimenopause and menopause
- Little evidence for SSRIs or SNRIs for menopausal symptoms
- Consider HRT and or CBT for low mood associated with menopause.

- Do not diagnose premature ovarian insufficiency on the basis of a single blood test.
- Do not routinely use anti-Müllerian hormone testing to diagnose premature ovarian insufficiency.

High doses

Joint BMS FSRH RCGP RCOG SfE and RCN Women's Health Forum safety alert - British Menopause Society (thebms.org.uk)

Oestrogen should not be regularly prescribed in doses higher than the upper limit listed in the individual Summary of Product Characteristics (SmPC) as these limits are informed by the results of clinical trials, to ensure patient safety.

If in exceptional circumstances a higher than licensed dose is deemed necessary for symptom control, informed consent should be obtained according to good medical practice guidance and patients must be made aware that treatment falls outside of reassuring safety evidence.

In addition, the dose of progestogen should be increased proportionately.

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Hip pain after menopause?

Gluteal Tendinopathy (Greater Trochanteric Pain Syndrome) may occur in menopausal women - Royal Orthopaedic Hospital - Gluteal Tendinopathy (roh.nhs.uk) and is linked to the reduction of oestrogen impacting on collagen production.

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Stock availability problems?

Prescribing available HRT products – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

HRT-Equivalent-preparations-7th-January-22.pdf (thebms.org.uk)

Stock availability and clinically equivalent preparations-

Links on the website page!

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Unscheduled bleeding

- Explain to women and people with a uterus that unscheduled vaginal bleeding is a common side effect of HRT within the first 3 months of treatment but should be reported at the 3-month review appointment, or review promptly if it occurs after the first 3 months (see recommendations on **endometrial cancer** in the NICE guideline on suspected cancer).

- Unscheduled bleeding after 6 months of starting HRT **should be reviewed** by a GP, with examination where suitable.

- Patients may be reluctant to stop HRT to see if bleeding settles due to the benefits of treatment for menopause symptoms which previously affected quality of life.

- Take a detailed history- more information on the website!

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What else can we do?

Webinars [Free Resources for Your Patients - NHS Somerset]

[Understanding the facts about Menopause and HRT with Dr Kathryn Patrick, Recorded 1 March 2023 – YouTube]

[Menopause and HRT Webinar with Dr Kathryn Patrick - YouTube BSL]

Check out resources available

Recent TV shows- some really important lived experiences to hear about

Listen to your patient

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Patient Education

- Menopause Symptom Checklist

Menopause and HRT patient webinar

- The Menopause service encourage all Somerset GP surgeries to embed the patient education webinar presented by Dr Kathryn Patrick onto their websites and direct patients to watch this ahead of any appointment to discuss menopause. This will ensure that the patient has an adequate knowledge to allow them to make informed decisions about their proposed treatment plan.
- Understanding the facts about Menopause and HRT with Dr Kathryn Patrick

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The Somerset NHS Menopause Service

Run by:

Dr Juliette Balfour and Dr Sophie Aldridge

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About the Service

- The Somerset NHS Menopause Service launched in April 2022. Funding has been agreed to continue the service until March 2024.
- The service is run by Dr Juliet Balfour from Glastonbury Surgery where a clinic is held once a week.
- Referrals to the service can only be made by GPs and is only available for patients registered with Somerset GP surgeries that are part of the Somerset ICB.
- Referrals should be sent to somicb.somersetnhsmenopauseservice@nhs.net which will be triaged by Dr Balfour.
- The majority of these referrals will receive **Advice & Guidance**. The turnaround for this is usually within **2-3 weeks**.
- Those who require a **face to face consultation** will be offered an appointment via text message from the surgery. The current wait time is around **12-14 weeks**.
- Once a patient has been seen in the clinic, Dr Balfour or Dr Aldridge will write to the referring GP with a detailed management plan.
- Should a follow up appointment be needed, this will be carried out by telephone.

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What to include in a referral

- Why specialist advice is needed
- What the patient is hoping for
- If there is a particular reason why the patient may need a face to face appointment
- What HRT has been tried before and at what dose
- A summary print out of past medical history and operations, medications, allergies and any blood test results from the last 2 years
- If the patient is under 45, please check oestradiol and FSH levels 6 weeks apart if possible. If still having fairly regular periods, the first blood test should be day 1-3 of the cycle. **You can still refer your patient even if the levels are normal**. Do not check FSH if the patient is on the combined pill or HRT.
- Oncology letters if a history of breast cancer or any hormone sensitive cancer
- Any letters from the Family History clinic.
- **If referring a patient to consider adding testosterone, please make sure they are already on transdermal oestrogen and have had blood tests to check oestradiol, testosterone and sex hormone binding globulin levels before their appointment. You can send these results with the referral letter or email afterwards if done later**.

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Face to Face appointment or GP Advice?

- Patients with complex medical histories when the HCP is not sure if HRT is a safe option e.g. significant active liver disease, a history of heart disease, VTE or stroke.
- Patients with complex gynaecological history such as endometriosis.
- Patients who have tied various HRT options but have not yet found something which works for them.
- Patients needing specialist advice on local oestrogen options for genitourinary syndrome of the menopause.
- Patients who would like to try adding in testosterone, if there is no HCP at the practice who has trained on how to do this. **Testosterone for women is now green on Somerset ICB Prescribing formulary if the HCP is competent to prescribe**.
- Older women over 60 (or 10 years since last period) keen to start or re-start HRT if the HCP is not confident about current guidelines.
- Patients with premature ovarian insufficiency or an early menopause
- Patients at high risk of osteoperosis
- Younger patients with possible perimenopausal symptoms but fairly regular periods and the HCP is not sure about the diagnosis.
- Patients on HRT with unscheduled bleeding but only after advice has been sought from gynaecology team and appropriately investigated.
- Patients with a strong family history of breast cancer or patients with a history of breast cancer or another hormone sensitive cancer.

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Patients not suitable for referral to the menopause service

- Patients with premature ovarian insufficiency or early menopause who mainly want to discuss fertility issues.
- Patients with unscheduled bleeding on HRT who have not yet been referred and/or seen by the gynaecology team to exclude pathology.
- Patients with breast or gynaecological cancers who are already under the Bristol or Bath breast or gynaecological oncology services. These patients should be referred to the combined oncology and menopause clinic at the relevant hospital.

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Questions

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Prescribing medications which are high risk in pregnancy

2023 Scorecard indicator

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Why?

Prioritisation of safety of medications in pregnancy and breastfeeding has not been high.

We know that approximately 81.2% of women use at least one medication during pregnancy (prescribed or OTC)[1].

In Somerset in 2019 we had approximately 5155 pregnancies which means over 4000 pregnancies exposed to medication.

In March 2018 we saw a strengthened regulatory position on the use of valproate in women and children of childbearing age needing a pregnancy prevention programme in place while having treatment.

According to MBRRACE-UK 2019, 13% of maternal deaths in pregnancy and the immediate period after giving birth were attributed to epilepsy or stroke.

There's been a huge focus on valproate nationally, but we see little else with regards to the safety of medications in pregnancy.

1. Medication use in pregnancy: a cross-sectional, multinational web-based study | BMJ Open [Accessed 12/08/2021]

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Aims

1. Reduce the prescribing of medication to people who can become pregnant with teratogenic potential without appropriate contraception and counselling in place.
2. GP/ clinician education and support
3. Improved patient interactions and pregnancy planning for those on long term medication/ with long term conditions
4. Improve informed consent
5. Improve our formulary resources on safe prescribing in pregnancy-
6. Medicines in pregnancy, children and lactation - NHS Somerset
7. Increase prescribing competency in lactation to support parents to reach their infant feeding goals.

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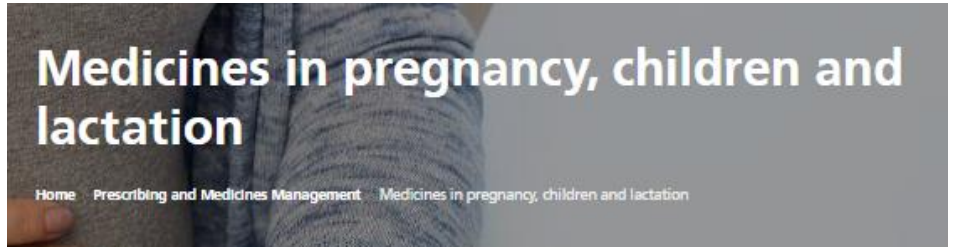
Website resources

[Medicines in pregnancy, children and lactation - NHS Somerset]

Click through to the medicines in pregnancy page



There is a wealth of information for us to use when considering medications prescribed for use in pregnancy, while breastfeeding and with children. It isn't always easy to find this information in one place so we have put together guidance and links for you to use when making appropriate decisions with your patients.

The information and links provided are for guidance, clinical decisions remain the responsibility of the practitioner; the intention is to help prescribers find evidence based information and does not replace input from appropriate professionals or constitute medical advice for individual patients.

Please contact sam.morris2@nhs.net with any suggested edits, or any additional resources you feel would be useful to be shared as these documents will be reviewed when appropriate.

Medicines in pregnancy | **Medicines in children** | **Medicines in lactation**

For infant feeding guidance, including cow's milk protein allergy (CMPA) prescribing guidelines see our Infant Feeding page.

COVID-19 vaccination: women of childbearing age, currently pregnant, planning a pregnancy or breastfeeding

Five reasons to get the COVID-19 vaccine if you're pregnant

Use of medicines in pregnancy and breastfeeding +

Safer Medicines in Pregnancy and Breastfeeding Consortium +

Safer Use of Medicines in Pregnancy – Planning Ahead Poster

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Website resources

NHS Somerset

Update on MHRA review into safe use of valproate – Update on MHRA review into safe use of valproate 12/12/22:
The CHM has advised that no one under the age of 55 should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment. Where possible, existing patients should be switched to another treatment unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risks do not apply.

Valproate use by women and girls MHRA updated guidance 11/02/2021 – *Information about the risks of taking valproate medicines during pregnancy.*

2022/23 Community Pharmacy Contractual Framework National Clinical Audit – *Reducing the potential for harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant.*
Specialist Pharmacy Service- SPS – **Epilepsy: treatment during pregnancy**
NHS Somerset formulary **Contraception** page
NHS Somerset formulary **Mental Health** page
Refer to the Somerset Traffic Lights System Document located on this **page** for details on individual drugs
Chapter 4.2 Epilepsy and other seizure disorders formulary page
NHS Somerset Medicines in pregnancy, children and lactation formulary page. The *Safer Use of Medicines in Pregnancy Poster- Planning Ahead* is now available, posters will be sent out to providers in early 2023.

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Medicines Management Safety Page- NEW!

Medication is the most common intervention in healthcare. Errors can happen at any point from prescribing to administering. In **2021/22** the number of prescription items dispensed in the community in England was 1.14 billion costing the NHS £9.69 billion.

The CQC has information for practices on how to respond to patient safety. **GP mythbuster 91: Patient safety alerts**

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. Please see here for the most recent **drug safety updates**. Practices should have procedures in place to action these updates.

MHRA Updates +

Potentially Addictive Medications +

Teratogenic Drugs and Safe Prescribing +

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NHS Somerset

Website resources

NHS Somerset formulary **Contraception** page

More information on the contraception page detailing effective contraception choices

Contraception in patients taking medication with teratogenic potential

Unfortunately no complete list exists of all medications which pose a safety issue to pregnancy, however we do have emerging data coming through with safety reviews happening. Medication risk can also vary depending on stage of pregnancy or time before conception. All patients taking medications, particularly those on long term treatment should be supported to make informed decisions about their contraceptive needs and pregnancy planning.

FSRH (February 2018) and MHRA (May 2019) guidance

Females of childbearing potential should be advised to use highly effective contraception if they or their male partners are taking known teratogenic drugs or drugs with potential teratogenic effects. Highly effective contraception should be used both during treatment and for the recommended duration after discontinuation to avoid unintended pregnancy. Pregnancy testing should be performed before treatment initiation to exclude pregnancy and repeat testing may be required.

Methods of contraception considered to be 'highly effective' include the long-acting reversible contraceptives (LARC) copper intrauterine device (Cu-IUD), levonorgestrel intrauterine system (LNG-IUS) and progestogen-only implant (IMP), and male and female sterilisation. For more information see the **FSRH CEU statement**, **MHRA drug safety update**, and the **UK teratogenic information service**.

Valproate medicines must not be used in women of childbearing potential unless the Pregnancy Prevention Program is in place. If you are involved in the care of female patients on valproate in the UK, see a **reminder of actions** required for this medicine.

In April 2022 the MHRA published guidance on **pregabalin and risks in pregnancy**. This information is relevant to patients taking pregabalin who are able to become pregnant.

Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed? New guidance from the MHRA from March 2019 on contraception methods and frequency of pregnancy testing to reduce inadvertent exposures during pregnancy in women/ people taking a medicine of teratogenic potential.

The Medicines for Women's Health Expert Advisory Group of the Commission on Human Medicines has developed an **aide-memoire table** to provide guidance to prescribers of medicines with teratogenic potential on the frequency of pregnancy testing needed to avoid exposure in pregnancy during treatment, depending on the chosen contraceptive method.

FSRH CEU Statement: Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects (February 2018) - Faculty of Sexual and Reproductive Healthcare

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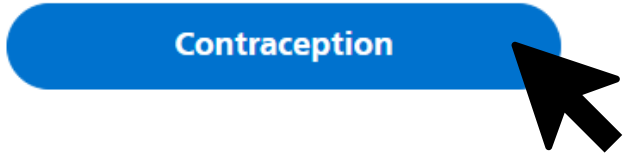
Highly effective contraception



- FSRH CEU Statement: Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects (February 2018)

Highly effective methods are based on less than 1% failure rate in typical use; Less effective methods are based on greater than 1% failure rate (6 – 9%) in typical use

NB FSRH: Drug Interactions with Hormonal Contraception Refer to guidance, BNF interactions and SmPC.

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Highly effective contraception

Pregnancy testing and contraception for pregnancy prevention during treatment with medicines of teratogenic potential

- Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?

Effectiveness of contraceptive in typical use[1]	Contraceptive method	Duration contraceptive method used / other situations	Pregnancy test needed before next teratogen prescription?
Highly effective methods **(Typical use failure rates less than 1%)**	Copper intrauterine device (copper IUD)	Established user more than 3wks to 5-10 yrs (depending on IUD[2])	No
	Levonorgestrel-releasing intrauterine system (LNG-IUS)	Established user more than 3wks to 3-5 yrs (depending on IUS[2])	No
	Progestogen Implant	Established user more than 3wks to 3yrs	No
		Established user (more than 3wks), but concurrent use of interacting medicines which may affect efficacy[3]	Yes + review / refer for contraceptive advice
Effective methods **(Typical use failure rates greater than 1%)** **Additional barrier methods are advised during teratogen use**	Depot medroxyprogesterone acetate (DMPA) subcutaneous (SC) or intramuscular (IM) injections[4]	Established user (more than 3wks + repeat injections on schedule) and less than 13 wks since last injection + documented as administered by healthcare professionals	No
		Established user (more than 3wks + repeat injections on schedule and less than 13 wks since last injection) but self-administered or undocumented administration	Yes, test if any suspected risk of pregnancy
		More than 13 wks since last injection (ie beyond recommended duration of use of last injection)	Yes + review / refer for contraceptive advice
	Combined hormonal contraceptives (pills, patches or vaginal ring) or progestogen-only pills	Established user (more than 3wks), reliable and consistent use	Yes, test if any suspected risk of pregnancy
		Established user (more than 3wks) but with unreliable or inconsistent use of method, eg: • missed pills, late patch • Diarrhoea or vomiting; • use of other interacting medicines that may affect efficacy[3]	Yes + review / refer for contraceptive advice
	Other methods or no contraception	Any duration of use of other methods	Yes + review / refer for contraceptive advice;
		No contraception	Assess need for contraception + test if any suspected risk of pregnancy + review / refer for contraceptive advice;

Explanatory notes:

1. Effectiveness of methods are based on failure rates in typical use (which includes risk of user error) rather than perfect use. Perfect use failure rates are similar for specific methods listed (0.03 – 0.6%) but risk of user error is higher for daily methods than for long acting reversible contraceptive (LARC) methods and are highest for methods used at time of sexual intercourse. Highly effective methods are based on less than 1% failure rate in typical use; Less effective methods are based on greater than 1% failure rate (6 – 9%) in typical use (Trussell J Contraceptive failure in the United States Contraception. 2011 May;83(5):397-404. doi: 10.1016/j.contraception.2011.01.021. Epub 2011 Mar 12)
2. Refer to Product Information for specific products; patients should be reviewed / referred for contraception advice at the end of the recommended duration of use
3. Implants are only considered as highly effective and combined hormonal contraceptives and progesterone-only pills are only considered as effective if interactions with any concurrent medicine are not a concern (see FSRH guidance on drug interactions with hormonal contraception)
4. DMPA (IM or SC) injection can be considered as highly effective if it is administered by healthcare professionals and continuous repeat use is documented as occurring within recommended duration of action (equivalent to perfect use, failure rate = 0.2%). Otherwise it is considered an effective contraceptive (typical use failure rate =6%). The same rationale should be used for other injection products with different recommended duration of action (eg Norethisterone Enanthate)

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Lactation and medicines

Infant feeding page

Information resources for safe prescribing +

GP and Healthcare Education +

The Somerset Medicines Management Team are pleased to share an Introduction to Breastfeeding and Safety of Prescribing in Lactation training. We will be recording a webinar to compliment this material with the Infant Feeding Leads from Yeovil District Hospital and Somerset Foundation Trust.

Somerset Medicines Management Information on Lactation and Safe Prescribing September 2022

- **Breastfeeding and Medication learning resources** – written by Dr Wendy Jones MBE, this resource includes the **Pharmacokinetics and transport of drugs into breastmilk** presentation as well as some other very valuable presentations that may be relevant to your practice.
- **GPIFN** is a resource put together by GPs. This has many very useful links and CPD opportunities suitable for all health care professionals.
- **eLearning for Healthcare- Infant feeding resource**.
- **ABM link to breastfeeding training for professionals**.
- **How to advise women on the safe use of medicines while breastfeeding** article in the Pharmaceutical Journal published in June 2021 written by Dr Wendy Jones MBE to share information for healthcare professionals.
- **Guidance sheets for providing remote care during the Covid-19 outbreak**
- Click the picture below for the **Unicef e-learning for GPs** page.

- Specialist Pharmacy Service (SPS): **Advising on medicines regimens during breastfeeding** (UKDILAS- UK Drugs In Lactation Service). The specialist UKDILAS service from SPS provides evidence-based information and advice to healthcare professionals on the safe use of medications in lactation, details for enquiries can be found on the **Breastfeeding enquires** page.
- **Drugs and Lactation Database (Lactmed)** The Drugs and Lactation Database contains information on drugs which may be used in lactation, a US resource cited by **NICE PH11** for use as a suitable supplementary resource for prescribers.
- **The Breastfeeding Network Drugs Factsheets** provided by the **Breastfeeding Network Drugs in Breastmilk service**, providing evidence-based information covering the most common issues affecting parents.

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Mental Health Prescribing - NHS Somerset

Mental Health in Pregnancy and Lactation

Perinatal Mental Health −

Please see our **Medicines used in Pregnancy** and **Breastfeeding and Medicines** pages for resources around prescribing in the perinatal period.

Depression/ antidepressant use in pregnancy and lactation.

Please see the NHS Somerset information on **prescribing SSRI's and SNRIs in pregnancy and lactation** January 2023.

Prescribing-SSRIs-and-SNRIs-in-pregnancy-and-lactation.pdf (nhssomerset.nhs.uk)

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Mental Health in Pregnancy and Lactation

Perinatal Mental Health

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General advice when prescribing SSRIs/SNRIs in pregnancy and lactation.

Prescribing-SSRIs-and-SNRIs-in-pregnancy-and-lactation.pdf (nhssomerset.nhs.uk)

Mental Health Prescribing - NHS Somerset

Medication	Drug-specific advice	RID
Sertraline	Sertraline is considered the antidepressant of choice for use in pregnancy and lactation. It may be continued throughout pregnancy and whilst breastfeeding if benefits out-weigh potential risks.	0.4%-2.2%
Citalopram	Citalopram may be continued throughout pregnancy and whilst breastfeeding if benefits out-weigh potential risks.	3.5%-5.4%
Duloxetine	Duloxetine may be continued throughout pregnancy and whilst breastfeeding if benefits out-weigh potential risks.	0.12%-1.12%
Fluoxetine	Fluoxetine should not be routinely initiated in pregnancy, or if planning to become pregnant or breastfeeding. However, if a mother is already well and stable whilst taking fluoxetine it may be advisable to continue treatment due to the risks associated with switching medication, or previous treatment success may indicate suitability to use. The average amount of fluoxetine found in breastmilk (RID) is higher than with other SSRIs and is long acting which may increase the risk of accumulation or side effects in an infant, the likelihood of side-effects reduces after 2-4 months postpartum. If fluoxetine is required by the mother/ parent, it is not a reason to discontinue breastfeeding.	1.6%-14.6%
Paroxetine	Paroxetine should not be routinely initiated in pregnancy or if planning to become pregnant due to the increased risk of discontinuation symptoms. However, if a mother is already well and stable whilst taking paroxetine it may be advisable to continue treatment due to the risks associated with switching medication. If paroxetine is required by the mother/ parent, it is an SSRI of choice in lactation and not a reason to discontinue breastfeeding.	1.2%-2.8%
Mirtazapine	Mirtazapine may be continued throughout pregnancy where clinically indicated with caution and whilst breastfeeding if benefits out-weigh potential risks. An alternative drug may be preferred, however, if a mother is already well and stable whilst taking mirtazapine it may be advisable to continue treatment due to the risks associated with switching medication. Low levels in milk are not anticipated to cause side-effects in an infant, especially if they are over 2 months of age. If mirtazapine is required by the mother/ parent, it is not a reason to discontinue breastfeeding. Mirtazapine is likely to cause drowsiness in the parent which can make bed-sharing unsafe, share safe sleep information (link in parent resources), discuss night feeding and possibility of needing help to breast/ chestfeed/ hold the baby if drowsy.	1.6%-6.5%
Venlafaxine	Venlafaxine should not be routinely initiated for women who are pregnant or planning to become pregnant due to the increased risk of discontinuation symptoms. However, if a mother is already well and stable whilst taking venlafaxine it may be advisable to continue treatment due to the risks associated with switching medication. If venlafaxine is required by the mother/ parent, it is not a reason to discontinue breastfeeding. Venlafaxine is likely to cause drowsiness in the parent which can make bed-sharing unsafe, share safe sleep information (link in parent resources), discuss night feeding and possibility of needing help to breast/ chestfeed/ hold the baby if drowsy.	6.8%-8.1%

RID= Relative infant Dose in lactation

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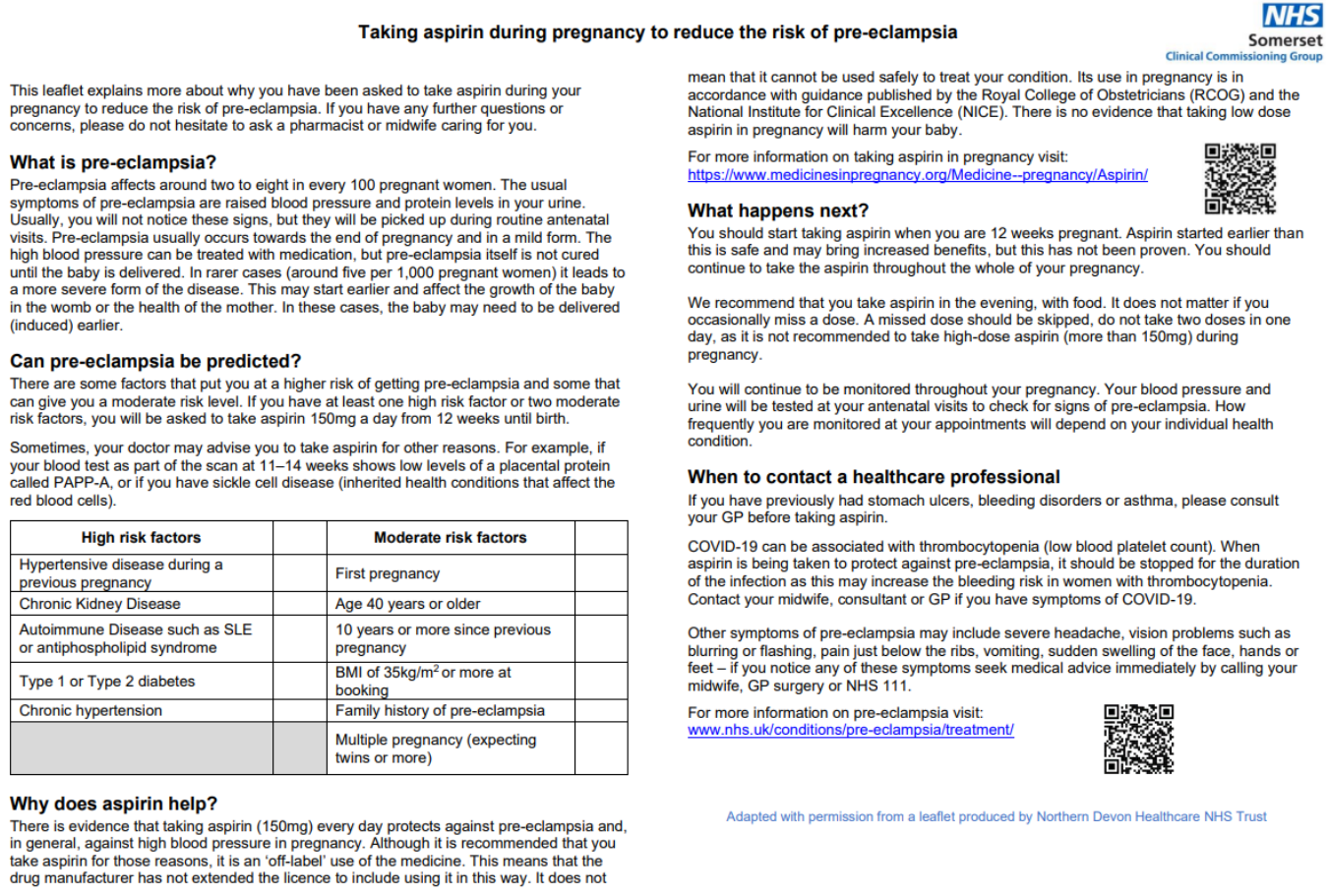
Accessibility to treatment

Aspirin PGD- for use in community pharmacy as part of the Somerset Minor Ailment Scheme

Taking-aspirin-to-reduce-the-risk-of-pre-eclampsia-A4-one-page-leaflet-Dec21.pdf (nhssomerset.nhs.uk)

Patient information leaflet ⟶

Folic Acid 5mg PGD approved and is on it's way…



Taking aspirin during pregnancy to reduce the risk of pre-eclampsia

NHS Somerset Clinical Commissioning Group

This leaflet explains more about why you have been asked to take aspirin during your pregnancy to reduce the risk of pre-eclampsia. If you have any further questions or concerns, please do not hesitate to ask a pharmacist or midwife caring for you.

What is pre-eclampsia?

Pre-eclampsia affects around two to eight in every 100 pregnant women. The usual symptoms of pre-eclampsia are raised blood pressure and protein levels in your urine. Usually, you will not notice these signs, but they will be picked up during routine antenatal visits. Pre-eclampsia usually occurs towards the end of pregnancy and in a mild form. The high blood pressure can be treated with medication, but pre-eclampsia itself is not cured until the baby is delivered. In rarer cases (around five per 1,000 pregnant women) it leads to a more severe form of the disease. This may start earlier and affect the growth of the baby in the womb or the health of the mother. In these cases, the baby may need to be delivered (induced) earlier.

Can pre-eclampsia be predicted?

There are some factors that put you at a higher risk of getting pre-eclampsia and some that can give you a moderate risk level. If you have at least one high risk factor or two moderate risk factors, you will be asked to take aspirin 150mg a day from 12 weeks until birth.

Sometimes, your doctor may advise you to take aspirin for other reasons. For example, if your blood test as part of the scan at 11–14 weeks shows low levels of a placental protein called PAPP-A, or if you have sickle cell disease (inherited health conditions that affect the red blood cells).

High risk factors		Moderate risk factors	
Hypertensive disease during a previous pregnancy		First pregnancy	
Chronic Kidney Disease		Age 40 years or older	
Autoimmune Disease such as SLE or antiphospholipid syndrome		10 years or more since previous pregnancy	
Type 1 or Type 2 diabetes		BMI of 35kg/m^2 or more at booking	
Chronic hypertension		Family history of pre-eclampsia	
		Multiple pregnancy (expecting twins or more)	

Why does aspirin help?

There is evidence that taking aspirin (150mg) every day protects against pre-eclampsia and, in general, against high blood pressure in pregnancy. Although it is recommended that you take aspirin for those reasons, it is an 'off-label' use of the medicine. This means that the drug manufacturer has not extended the licence to include using it in this way. It does not mean that it cannot be used safely to treat your condition. Its use in pregnancy is in accordance with guidance published by the Royal College of Obstetricians (RCOG) and the National Institute for Clinical Excellence (NICE). There is no evidence that taking low dose aspirin in pregnancy will harm your baby.

For more information on taking aspirin in pregnancy visit:
https://www.medicinesinpregnancy.org/Medicine--pregnancy/Aspirin/

What happens next?

You should start taking aspirin when you are 12 weeks pregnant. Aspirin started earlier than this is safe and may bring increased benefits, but this has not been proven. You should continue to take the aspirin throughout the whole of your pregnancy.

We recommend that you take aspirin in the evening, with food. It does not matter if you occasionally miss a dose. A missed dose should be skipped, do not take two doses in one day, as it is not recommended to take high-dose aspirin (more than 150mg) during pregnancy.

You will continue to be monitored throughout your pregnancy. Your blood pressure and urine will be tested at your antenatal visits to check for signs of pre-eclampsia. How frequently you are monitored at your appointments will depend on your individual health condition.

When to contact a healthcare professional

If you have previously had stomach ulcers, bleeding disorders or asthma, please consult your GP before taking aspirin.

COVID-19 can be associated with thrombocytopenia (low blood platelet count). When aspirin is being taken to protect against pre-eclampsia, it should be stopped for the duration of the infection as this may increase the bleeding risk in women with thrombocytopenia. Contact your midwife, consultant or GP if you have symptoms of COVID-19.

Other symptoms of pre-eclampsia may include severe headache, vision problems such as blurring or flashing, pain just below the ribs, vomiting, sudden swelling of the face, hands or feet – if you notice any of these symptoms seek medical advice immediately by calling your midwife, GP surgery or NHS 111.

For more information on pre-eclampsia visit:
www.nhs.uk/conditions/pre-eclampsia/treatment/

Adapted with permission from a leaflet produced by Northern Devon Healthcare NHS Trust

Taking aspirin to reduce the risk of pre-eclampsia leaflet v1.0 December 2021 Working Together to Improve Health and Wellbeing Page 1 of 1

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MHRA Warnings

Isotretinoin (Roaccutane▼): new safety measures to be introduced in the coming months, including additional oversight on initiation of treatment for patients under 18 years

Isotretinoin (Roaccutane▼): reminder of important risks and precautions – ↳**Reminder of strict precautions on prescribing including conditions on Pregnancy Prevention Programme.**

Topiramate (Topamax): start of safety review triggered by a study reporting an increased risk of neurodevelopmental disabilities in children with prenatal exposure

Modafinil (Provigil): increased risk of congenital malformations if used during pregnancy

Valproate (Epilim▼, Depakote▼) pregnancy prevention programme: updated educational materials

Ondansetron: small increased risk of oral clefts following use in the first 12 weeks of pregnancy

Magnesium sulfate: risk of skeletal adverse effects in the neonate following prolonged or repeated use in pregnancy

Carbimazole: increased risk of congenital malformations; strengthened advice on contraception

Codeine: very rare risk of side-effects in breastfed babies ↳Breastfed babies might very rarely develop side-effects due to the presence of morphine in breast milk. (due to hypermetabolism)

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CQC Searches

GP mythbuster 12: Accessing medical records and carrying out clinical searches

Search Categories:

3. MHRA/Central Alerting System (CAS)/drug safety update alerts to check provider has taken appropriate action in response

- Valproate, valproic acid, carbimazole, modafinil, topiramate and pregabalin: teratogenicity risk.

- Ardens CQC

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Pregnancy Prevention Programmes

- The retinoid medicines that have a Pregnancy Prevention Programme as a condition of the licence are oral isotretinoin (Roaccutane▼) for severe acne, oral acitretin (Neotigason▼) for severe psoriasis, and oral alitretinoin (Toctino▼) for chronic severe hand eczema. The regulatory requirement for a Pregnancy Prevention Programme has been in place for female patients taking these oral retinoids since 2005.
- Search Results - (emc) (medicines.org.uk)
- Valproate should not be prescribed to female children or women of childbearing potential unless other treatments are ineffective or not tolerated and that any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the Pregnancy Prevention Programme
- Search Results - (emc) (medicines.org.uk)

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PPP

- [medicines.org.uk- isotretinoin information]

FOR HEALTHCARE PROFESSIONAL USE ONLY

Prescriber Checklist Acknowledgement Form for Prescribing Isotretinoin to Female Patients

The potential for pregnancy must be assessed for all female patients prescribed Isotretinoin.

A woman has a potential for pregnancy if one of the following applies:

Is a sexually mature woman who:

1. has not had a hysterectomy or bilateral oophorectomy
2. is not in a natural postmenopause for a minimum of 24 consecutive months (i.e., menstruated at a certain point in the last 24 consecutive months).

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PPP

- Epilim 200 mg Gastro-resistant tablets - Risk Management Materials - (emc) (medicines.org.uk)
- Valproate Annual Risk Acknowledgement Form
- Guide for healthcare professionals

Valproate ▼ (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Sodium Valproate, Syonell, Valpal, Belvo & Dyzantil)

Contraception and Pregnancy Prevention – Important information to know

- Valproate is an effective medicine for epilepsy and bipolar disorder.
- Valproate can seriously harm an unborn baby when taken during pregnancy.
- Always use effective contraception at all times during your treatment with valproate.
- It is important to visit your specialist to review your treatment at least once each year.

▼ These medicines are subject to additional monitoring. Report any side effects to **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store.

Keep this card safe so you always know what to do.

Important information for all girls and women who could become pregnant

Valproate ▼: Contraception and Pregnancy Prevention

prevent
valproate pregnancy prevention programme

What you must do

- Read the package leaflet carefully before use.
- Never stop taking valproate without discussing it with your doctor as your condition may become worse.
- If you are thinking about having a baby, do not stop using valproate and contraception before you have talked to your doctor.
- If you think you are pregnant, do not stop using valproate. Make an urgent appointment with your GP.
- Ask your doctor to give you the Patient Guide for **prevent** – the valproate pregnancy prevention programme.

MAT-GB-2003304 (V2.0) November 2021

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Quality Improvement Incentive Scheme

NHS Somerset

	Other	Medicines in Pregnancy	**Medications to avoid in pregnancy due to increased risk - Contraception and planning ahead of pregnancy reviews needed.** Patients biologically able to become pregnant taking warfarin, rivaroxaban, apixaban, dabigatran, carbimazole, modafinil, topiramate, pregabalin, zonisimide, valproate, valproic acid, carbamazepine, phenytoin, phenobarbital, atorvastatin, fluvastatin, pravastatin sodium, rosuvastatin, simvastatin, ezetimibe, methotrexate, isotretinoin, epiduo or differin. This is not an exhaustive list, refer to individual SPCs, MHRA warnings and Pregnancy Prevention Programmes. Not coded as infertile, post menopausal or fitted with a LARC. To review.	09/04/2023	**3233**	**108**

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Responsibility

The Montgomery Case (rcpsg.ac.uk)

This case was heard at the UK Supreme Court in July 2014 before seven Justices following failed appeals in the Court of Session and the Inner House. The involvement of seven justices in this final appeal is of particular importance as this is the number of justices required to change or overrule a previous House of Lords ruling; in this case, the ruling in Sidaway.

The argument in this appeal was that is not appropriate to use the accepted practice of a body of reasonable medical practitioners when consent is considered. It should be viewed differently from the process of diagnosis or treatment. The relevant guidance from the GMC was reviewed and this supported the argument that it was the doctor's role to provide a patient with all the information to allow them to make a balanced judgement between different options.

All seven of the Justices supported the appeal.

The law on consent has progressed from doctor focused to patient focused. The practice of medicine has moved significantly away from the idea of the paternalistic doctor who tells their patient what to do, even if this was thought to be in the patient's best interests.

A patient is autonomous and should be supported to make decisions about their own health and to take ownership of the fact that sometimes success is uncertain, and complications can occur despite the best treatment.

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Research

Women's experiences of over-the-counter and prescription medication during pregnancy in the UK: findings from survey free-text responses and narrative interviews | BMJ Open >>> Full PDF (bmj.com)

| BPAS

Optimizing Prepregnancy Cardiovascular Health to Improve Outcomes in Pregnant and Postpartum Individuals and Offspring: A Scientific Statement From the American Heart Association | Circulation (ahajournals.org)

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A reminder to all…

NHS Somerset

[Overview | Babies, children and young people's experience of healthcare | Guidance | NICE]

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Questions

Thank you

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