

<u>Formu</u>	lary	HRT	items

	Oral	Transdermal patch	Implant	Topical
Sequential HRT	1 st line: Elleste Duet 2 nd line: Femoston*	Not recommended as no added benefit	N/A	N/A
Continuous combined HRT	1 st line: Kliovance 2 nd line: Premique low-dose* 3 rd line: Tibolone	Evorel Conti	N/A	N/A
Oestrogen only HRT	Elleste solo	Estradot	Estradiol implants	Aerodiol nasal spray* Sandrena gel*
Vaginal HRT	1 st line: Ortho-Gynest cream 2 nd line: Vagifem tablets*			J

References:

* Not to be stocked by the Hospital Pharmacy

1. Review of the evidence on long-term safety of HRT. Current Problems in Pharmacovigilance. Oct 2004;30:4-7

2. Burger et al. Practical recommendations for hormone replacement therapy in the peri- and post menopause. Climacteric 2004;7

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HRT Advice for Prescribers

Benefits of HRT

For the treatment of **menopausal symptoms** the benefits of short-term HRT are considered to outweigh the risks in the majority of women. Each decision to start HRT should be made on an individual basis with a fully informed woman.

Need for regular review

In all cases, it is good practice to use the lowest effective dose for the shortest possible time and to review the need to continue treatment at least annually. This review should take into account new knowledge and any changes in a woman's risk factors and personal preferences.

- For women without a uterus: oestrogen-only therapy is appropriate.
- For women with a uterus: oestrogen plus progestogen is recommended. However, women should be fully informed of the added risk of breast cancer and be involved in the decision-making process.

Risks of HRT

The main risks associated with HRT are summarized overleaf.

HRT increases the risk of breast cancer and combined oestrogen plus progesterone has a higher risk than oestrogen alone. However in women with an intact uterus the addition of progesterone reduces their risk of endometrial cancer.

HRT should no longer be the therapy of first choice for prevention of osteoporosis

- For postmenopausal women who are at an increased risk of fracture and are aged over 50 years, HRT should be used to prevent osteoporosis ONLY in those who are intolerant of, or contraindicated for, other osteoporosis therapies
- Women who are receiving HRT for their menopausal symptoms will benefit from the effect of HRT on osteoporosis prevention whilst on treatment
- Healthy women who have no menopausal symptoms should be advised against taking HRT as the risks outweigh the benefits

Please note:

HRT does NOT prevent coronary heart disease or a decline in cognitive function and should NOT be prescribed for these purposes.

Contraindications:

HRT remains contraindicated in women who have had breast cancer.

Refer to Summary of Product Characteristics for contraindications and precautions for use.

1. Current Problems in Pharmacovigilance, Volume 30, October 2004.

CSM Summary of the risks and benefits associated with using HRT¹

Condition	Age of woman (yr)	Number of cases/ 1000 non-HRT		Extra number of cases in 1000 HRT users for 5 years HRT use over the same period*		
Cumulative cancer risk over 5 years			Oestrogen-only	Combined HRT		
Breast cancer Million Women Study	50-64		14ª	1.5 (±1.5)	6 (±1)	
		CEE ^b	CEE + MPA ^b			
WHI	50-79	15	16	No significant effect	4 (±4)	
Endometrial cancer	50-69		3 ^b	5 (±1)°	Cannot be estimated ^d	
Ovarian cancer	50-69	3		1 (±1)	Not known	
Cardiovascular r	isks over 5 year:	3				
	T	CEE ^b	CEE + MPA ^b		Harriston 1967 Distribution of the State o	
Stroke	50-59 60-69	8 15	3 . 11	2 (±2) 6 (±4)	1 (±1) 4 (±3)	
VTE	50-59	6.5	3	1 (±1)	4 (±2)	
7 1 25	60-69	11.5	8	4 (±4)	9 (±5)	
Benefits over 5 years				Reduced number of cases in 1000 HRT users over the same period		
	#	CEE ^b	CEE + MPA ^b			
Colorectal cancer	50-59	6	3	No significant effect	1 (±1)	
	60-69	10	8		3 (±2)	
Fracture of neck	50-59	0.5	1.5	0.3 (±0.5)	0.3 (±1)	
of femur	60-69	5.5	5.5	3 (±2)	3 (±2)	

Numbers are best estimates (± approximate range from 95% Confidence Intervals).

^{*} All values are from the WHI trial unless otherwise stated.

^a A cumulative risk of 14 cases/1000 non-HRT users over 5 years has been used to facilitate comparison of the MWS and the WHI studies.

b Estimates from the placebo groups of the WHI trial.
c Relative risk associated with 5 years' use of oestrogen-only HRT (RR = 2.8[2.3-3.5] from meta-analysis.

^d Risk cannot be reliably estimated - the addition of a progestogen for at least 12 days per month greatly reduces the additional risk of endometrial cancer due to unopposed oestrogen, but the magnitude of the reduction is poorly defined at present.