

oxytocin required, remove at least 30 minutes before oxytocin administration, for information on when to remove the delivery system—consult product literature

- **UNLICENSED USE** Misoprostol doses for termination of pregnancy may differ from those in product literature.

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: MISOPROSTOL VAGINAL DELIVERY SYSTEM (*MYSOLELLE*[®]): REPORTS OF EXCESSIVE UTERINE CONTRACTIONS (TACHYSYSTOLE) UNRESPONSIVE TO TOCOLYTIC TREATMENT (FEBRUARY 2018)

Mysodelle[®] can cause excessive uterine tachysystole that may not respond to tocolytic treatment. Monitor patients closely and remove the vaginal delivery system immediately in cases of excessive or prolonged uterine contractions, at the onset of labour, or if there is clinical concern for mother or baby.

Be prepared to administer tocolytic therapy—if needed, it can be administered immediately after removal of *Mysodelle*[®].

• CONTRA-INDICATIONS

MYSOLELLE[®] VAGINAL DELIVERY SYSTEM Before 36 weeks' gestation · chorioamnionitis (unless adequate prior treatment initiated) · fetal malpresentation · placenta praevia · suspicion or evidence of fetal compromise · unexplained vaginal bleeding after 24 weeks gestation · uterine abnormality · uterine scar

• CAUTIONS

- ▶ When used for termination of pregnancy Cardiovascular disease · risk factors for cardiovascular disease
- MYSOLELLE[®] VAGINAL DELIVERY SYSTEM** Modified Bishop score greater than 4

• SIDE-EFFECTS

- ▶ **Common or very common** Nausea · neonatal respiratory depression · rash · transient tachypnoea of the newborn · vomiting
 - ▶ **Uncommon** Genital pruritus · hypoxic-isaemic encephalopathy · uterine rupture
- **BREAST FEEDING** Manufacturer advises avoid—present in milk, and may cause diarrhoea in nursing infants. [EVG†](#) Tertiary sources state present in milk but amount probably too small to be harmful; to further reduce risk following termination of pregnancy, consider interrupting breastfeeding for 5 hours after a dose. [D](#)

• HANDLING AND STORAGE

MYSOLELLE[®] VAGINAL DELIVERY SYSTEM Manufacturer advises store in a freezer (-10 to -25°C); no thawing required prior to use.

• PATIENT AND CARER ADVICE

Driving and skilled tasks Manufacturer advises patients should be cautioned on the effects on driving and performance of skilled tasks—increased risk of dizziness.

• NATIONAL FUNDING/ACCESS DECISIONS

MYSOLELLE[®] VAGINAL DELIVERY SYSTEM

All Wales Medicines Strategy Group (AWMSG) decisions
AWMSG No. 3627

The *All Wales Medicines Strategy Group* has advised (March 2018) that misoprostol (*Mysodelle*[®]) is recommended as an option for use within NHS Wales for the induction of labour in women with an unfavourable cervix, from 36 weeks gestation, in whom induction is clinically indicated.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Vaginal delivery system

- **Mysodelle** (Ferring Pharmaceuticals Ltd)

Misoprostol 7 microgram per 1 hour Mysodelle 200micrograms vaginal delivery system | 5 unit [PoM](#) £465.00

Tablet

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- ▶ **Misoprostol (Non-proprietary)**

Misoprostol 200 microgram Misoprostol 200microgram vaginal tablets | 4 tablet [PoM](#) [S](#) (Hospital only)

- ▶ **Topogyne** (Nordic Pharma Ltd)

Misoprostol 400 microgram Topogyne 400microgram tablets | 16 tablet [PoM](#) £128.00 (Hospital only)

6 Vaginal and vulval conditions

Vaginal and vulval conditions

Management

Symptoms are often restricted to the vulva, but infections almost invariably involve the vagina which should also be treated. Applications to the vulva alone are likely to give only symptomatic relief without cure.

Aqueous medicated douches may disturb normal vaginal acidity and bacterial flora.

Topical anaesthetic agents give only symptomatic relief and may cause sensitivity reactions. They are indicated only in cases of pruritus where specific local causes have been excluded.

Systemic drugs are required in the treatment of infections such as gonorrhoea and syphilis.

Vaginal and vulval changes

Topical HRT for vaginal atrophy

A cream containing an oestrogen may be applied on a short-term basis to improve the vaginal epithelium in *menopausal atrophic vaginitis*. It is **important** to bear in mind that topical oestrogens should be used in the **smallest effective** amount to minimise systemic effects. Modified-release vaginal tablets and an impregnated vaginal ring are now also available.

The risk of endometrial hyperplasia and carcinoma is increased when *systemic* oestrogens are administered alone for prolonged periods. The endometrial safety of long-term or repeated use of *topical* vaginal oestrogens is uncertain; treatment should be reviewed at least annually, with special consideration given to any symptoms of endometrial hyperplasia or carcinoma.

Topical oestrogens are also used in postmenopausal women before vaginal surgery for prolapse when there is epithelial atrophy.

Non-hormonal preparations for vaginal atrophy

Several non-hormonal vaginal moisturisers are available and some are prescribable on the NHS (consult Drug Tariff).

Vaginal and vulval infections

Effective specific treatments are available for the common vaginal infections.

Fungal infections

Candidal vulvitis can be treated locally with cream, but is almost invariably associated with vaginal infection which should also be treated. *Vaginal candidiasis* is treated primarily with antifungal pessaries or cream inserted high into the vagina (including during menstruation). Single-dose preparations offer an advantage when compliance is a problem. Local irritation may occur on application of vaginal antifungal products.

Imidazole drugs (clotrimazole p. 875, econazole nitrate p. 875, fenticonazole nitrate p. 876, and miconazole p. 876) are effective against candida in short courses of 1 to 14 days according to the preparation used; treatment can be repeated if initial course fails to control symptoms or if