Prescribing Information
Oestrogel (estradiol) Pump-Pack 750 micrograms/actuation Gel

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC). **Presentation**: Transdermal gel. One gram of gel contains 0.6 mg of the active ingredient, Estradiol (0.06% w/w). Each pump actuation delivers 1.25 g of gel which contains 0.75 mg of Estradiol. This medicine contains 0.5 g alcohol (ethanol) in each dose of 1.25 g gel. **Indication:** 1. Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women. 2. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. The experience treating women older than 65 years is limited. **Posology and method of administration:** *Menopausal and postmenopausal symptoms:* The usual starting dose is 2 pumps (2.5 g containing 1.5 mg estradiol) once daily. If effective relief is not obtained after one month's treatment, this may be increased to a maximum of four pumps (5 g containing 3.0 mg estradiol) daily. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. *Postmenopausal osteoporosis:* The minimum effective dose is 2.5 g Oestrogel once daily for most patients. Oestrogel is an oestrogen-only product to be administered daily on a continuous basis for women without a uterus. In women with an intact uterus it is recommended to add a progestogen for at least 12 days of each month, in accordance with the manufacturers' recommendation. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestogen in hysterectomised women. The pump pack will require priming before using a new pump pack for the first time. The first dose dispensed should be discarded. The gel should be applied to at least 750 cm^2 of clean, dry, intact areas of skin (e.g. arms, shoulders, inner thighs). It should not be applied on or near the breasts or on the vulval region. A frequent change in application sites is recommended. The patient should apply the gel herself and avoid skin contact with others, particularly a male partner, for at least 1 hour after application. Wash hands with soap and water after applying the gel. Patients should be informed that children should not come in contact with the area of the body where Oestrogel was applied on. **Contraindications:** Known, past or suspected breast cancer; known or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism (deep vein thrombosis, pulmonary embolism), known thrombophilic disorders, active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction); acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal; known hypersensitivity to the active substances or to any of the excipients; porphyria**. Warnings and Precautions for use:** For the treatment of postmenopausal symptoms: HRT should only be initiated for symptoms that adversely affect quality of life. The risks and benefits should be reviewed annually and HRT only continued as long as the benefit outweighs the risk. A personal and family medical history should be taken before initiating or reinstituting HRT. Periodic check-ups are recommended during treatment. Women should be advised what changes in their breasts should be reported to their doctor or nurse. Physical examination and investigations including appropriate imaging tools should be carried out according to the clinical needs of the patient. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment since they may recur or be aggravated during treatment with Oestrogel: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for oestrogen-dependent tumours; hypertension; liver disorders; diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; history of endometrial hyperplasia; epilepsy; asthma and otosclerosis. Oestrogel should be discontinued if a contraindication is discovered or the following occur: jaundice or deterioration in liver function; significant increase in blood pressure; new onset of migraine-type headache; pregnancy. In women with an intact uterus the risk of endometrial hyperplasia and carcinoma is increased when oestrogens are administered alone for prolonged periods of time. The addition of a progestogen cyclically for at least 12 days per month/28 day cycle or continuous combined oestrogen-progestogen therapy in non-hysterectomised women prevents the excess risk associated with oestrogen-only HRT. Break through bleeding and spotting may occur during the first months of treatment but if they occur after some time on therapy or continue after treatment has been discontinued the reason should be investigated. Unopposed oestrogen stimulation may lead to premalignant or malignant transformation in the residual foci of endometriosis. Therefore, the addition of progestogens to oestrogen replacement therapy should be considered in women who have undergone hysterectomy because of endometriosis if they are known to have residual endometriosis. Evidence shows an increased risk of breast cancer in women taking combined oestrogen-progestogen or oestrogen-only HRT that is dependent on the duration of taking HRT. HRT, especially oestrogen-progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer. Epidemiological evidence from a large meta-analysis suggests a slightly increased risk of ovarian cancer in women taking oestrogen-only or combined oestrogen-progestogen HRT which becomes apparent within 5 years of use and diminishes over time after stopping. HRT is associated with a 1.3 to 3-fold risk of developing venous thromboembolism. The occurrence of such an event is more likely in the first year of HRT than later. It is recommended to stop HRT 4 to 6 weeks prior to elective surgery if prolonged immobilisation is to follow. The benefit-risk of HRT should be considered in women already on chronic anticoagulant treatment. If venous thromboembolism occurs during treatment, HRT should be discontinued. Patients should contact their doctors immediately if they have potential thromboembolic symptoms. The relative risk of coronary artery disease (CAD) during use of combined oestrogen + progestogen HRT is slightly increased. As the baseline absolute risk of CAD is strongly dependent on age, the number of extra cases of CAD due to oestrogen + progestogen use is very low in healthy women close to menopause, but will rise with more advanced age. Combined oestrogen-progestogen and oestrogen-only therapy are associated with up to a 1.5-fold increase in risk of ischaemic stroke. The relative risk does not change with age or time since menopause. However, as the baseline risk of stroke is strongly age-dependent, the overall risk of stroke in women who use HRT will increase with age. Care should be taken with women with cardiac or renal dysfunction since oestrogens may cause fluid retention. Women with pre-existing hypertriglyceridaemia should be followed closely during oestrogen replacement or HRT since pancreatitis can result from rare cases of large increases in plasma triglycerides. Oestrogens increase thyroid binding globulin (TBG), leading to increased circulating total thyroid hormone. Other binding proteins may be elevated in serum, i.e. corticoid binding globulin (CBG), sex-hormone-binding globulin (SHBG) leading to increased circulating corticosteroids and sex steroids respectively. Other plasma proteins may be increased (angiotensinogen/renin substrate, alpha-I-antitrypsin, ceruloplasmin). HRT use does not improve cognitive function. There is some evidence of increased risk of probable dementia in women who start HRT after the age of 65. It may cause burning sensation on damaged skin. This product is flammable until dry. **Interactions:** Patients should avoid strong skin cleaners and detergents, skin products of high alcoholic content (e.g. astringents, sunscreens) and keratolytics which may alter the barrier structure or function of the skin. Use of any concomitant skin medication which alters skin production (e.g. cytotoxic drugs) should be avoided. The metabolism of oestrogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants (e.g. phenobarbital, phenytoin, carbamazepine) and anti- infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz). Ritonavir and nelfinavir exhibit inducing properties when used concomitantly with steroid hormones. Herbal preparations containing St John's wort (Hypericum perforatum) may induce the metabolism of oestrogens. Transdermally applied oestrogens may be less affected by enzyme inducers than oral hormones. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Hormone contraceptives containing oestrogens shown to significantly decrease plasma concentrations of lamotrigine when co-administered. This may reduce seizure control. **Pregnancy and lactation:** Oestrogel is not indicated in pregnancy. If pregnancy occurs during medication with Oestrogel, the treatment should be withdrawn immediately. The data relating to inadvertent foetal exposure to oestrogens indicate no teratogenic of foetotoxic effects. Oestrogel is not indicated during lactation. **Undesirable effects:** Based on post marketing experience, the following occur at a frequency not known (cannot be estimated from the available data) with Oestrogel: nausea, dizziness, headache, alopecia, pruritus. The following undesirable effects are observed with HRT products used in menopause at a common frequency (>1/100; <1/10); headache, nausea, abdominal pain, breast swelling/pain, breast enlargement, dysmenorrhoea, menorrhagia, metrorrhagia, leucorrhoea, endometrial hyperplasia, weight change (increase or decrease), water retention with peripheral oedema, uncommon frequency (≥1/1,000; <1/100) ; depression, mood swings, vertigo, migraine, venous thromboembolic disease, flatulence, vomiting, pruritus, benign breast neoplasm, increased volume of uterine, leiomyoma, vaginitis/vaginal candidiasis, asthenia, rare frequency, (≥1/10,000; <1/1,000) ; glucose intolerance, change in libido, aggravation of epilepsy, arterial hypertension, liver function tests abnormalities, skin decolouration, acne, galactorrhoea, anaphylactic reaction (in women with past history of allergic reaction). The following risks apply in relation to systemic oestrogen/progestogen treatment: breast cancer; endometrial cancer; ovarian cancer; venous thromboembolism; coronary artery disease; ischaemic stroke. For further information on side effects and risk estimates, please consult the SPC. **Overdose:** Overdosage is unlikely with transdermal applications. Overdoses of oestrogen may cause breast tenderness, nausea and withdrawal bleeding. These signs disappear when the treatment is stopped or when the dose is reduced. There are no specific antidotes and treatment should be symptomatic**. NHS Price:** 80g dispenser £6.17. **Legal category:** POM. **Marketing Authorisation number:** PL 28397/0002. **Marketing Authorisation Holder:** Besins Healthcare, Rue Washington 80, 1050 Ixelles, Belgium. **Date of preparation of Prescribing Information:** December 2023 OES/2023/046

Adverse events should be reported.
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Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 0203 862 0920
Email: pharmacovigilance@besins-healthcare.com

Prescribing Information Utrogestan (micronised progesterone) 100 mg capsules

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: Soft white capsule containing 100 mg micronised progesterone. **Indication:** Adjunctive use with oestrogen in post-menopausal women with an intact uterus as hormone replacement therapy (HRT). **Posology and method of administration:** In women receiving estrogen replacement therapy there is an increased risk of endometrial cancer which can be countered by progesterone administration. The recommended dose is 200 mg daily at bedtime for twelve days in the last half of each therapeutic cycle (beginning on Day 15 of the cycle and ending on Day 26). Withdrawal bleeding may occur in the following week. Alternatively, 100 mg can be given at bedtime from Day 1 to Day 25 of each therapeutic cycle, withdrawal bleeding being less with this treatment schedule. Dose for elderly is the same. Not indicated in the paediatric population. Oral capsules which should not be taken with food as this increases the bioavailability of the capsules. For full details of usage see SPC. **Contraindications:** When used in conjunction with estrogens, Utrogestan should not be used in patients with any of the following conditions: known hypersensitivity to the active substances, soya lecithin, peanut or to any of the excipients, known past or suspected breast cancer; known or suspected estrogen-dependent malignant tumours (e.g genital tract carcinoma) undiagnosed genital bleeding; ; previous or current thromboembolism disorders (e.g. deep venous thrombosis, pulmonary embolism) or thrombophlebitis; known thrombophilic disorders; acute liver disease or history of liver disease as long as liver function tests have failed to return to normal; porphyria; cerebral haemorrhage; breast-feeding. **Warnings and Precautions for use:** For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. A careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk. Utrogestan 100 mg Capsules are not suitable; in confirmed pregnancy; in the treatment of premature labour, or as a contraceptive. Before initiating or reinstituting HRT, a complete personal and family medical history should be taken. Women should be encouraged to be aware of their breasts and report any changes to their doctor or nurse. Investigations, including appropriate imaging tools, e.g. mammography, should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment since they may recur or be aggravated during treatment with Utrogestan 100 mg capusles; leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders, risk factors for oestrogen dependent tumours (e.g. 1st degree heredity for breast cancer), hypertension, liver disorders (e.g. liver adenoma); diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; a history of endometrial hyperplasia; epilepsy; asthma; otosclerosis; depression; photosensitivity. Therapy should be immediately discontinued in case a contra-indication is discovered and in the following situations: jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine- type headache, pregnancy, sudden or gradual, partial or complete loss of vision; proptosis or diplopia, papilloedema, retinal vascular lesions. Endometrial hyperplasia and carcinoma; the addition of progesterone for at least 12 days per month/28 day cycle or continuous combined estrogen-progestogen therapy in non-hysterectomised women prevents the excess risk associated with estrogen-only HRT. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated. Breast cancer; the overall evidence suggests an increased risk of breast cancer in women taking combined estrogen-progestogen and possibly also estrogen-only HRT, that is dependent on the duration of taking HRT. The excess risk becomes apparent within a few years of use but returns to baseline within a few (at most five) years after stopping treatment. HRT, especially estrogen-progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer. Ovarian cancer; epidemiological evidence from a large meta-analysis suggests a slightly increased risk in women taking estrogen-only or combined estrogen-progestogen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping. HRT is associated with a 1.3-3-fold risk of developing venous thromboembolism (VTE). The occurrence of such an event is more likely in the first year of HRT than later. If prolonged immobilisation is to follow elective surgery temporarily stopping HRT 4 to 6 weeks earlier is recommended. Women already on chronic anticoagulant treatment require careful consideration of the benefit-risk of use of HRT. If VTE develops after initiating therapy, the drug should be discontinued. Patients should be told to contact their doctors immediately when they are aware of a potential thromboembolic symptom. The relative risk of coronary artery disease during use of combined estrogen + progestogen HRT is slightly increased. Combined estrogen-progestogen and estrogen-only therapy are associated with an up to 1.5-fold increase in risk of ischaemic stroke. HRT use does not improve cognitive function. There is some evidence of increased risk of probable dementia in women who start using continuous combined or estrogen-only HRT after the age of 65. Utrogestan 100 mg capsules contain soybean lecithin and may cause hypersensitivity reactions (urticarial and anaphylactic shock in hypersensitive patients). As there is a possible relationship between allergy to soya and allergy to peanut, patients with peanut allergy should avoid using Utrogestan 100mg Capsules. **Interactions:** drugs known to induce the hepatic CYP450-3A4 (such as barbiturates, anti-epileptic agents (phenytoin, carbamazepine), rifampicin, phenylbutazone, bromocriptine, spironolactone, griseofulvin, some antibiotics (ampicillins, tetracyclines) and herbal products containing St. John's wort, may increase metabolism and the elimination of progesterone. Ketokonazole and other inhibitors of CYP450-3A4 such as ritonavir and nelfinavir may increase bioavailability of progesterone. Utrogestan 100mg may raise the plasma concentration of ciclosporin, diazepam, tizanidine. Aminogluthethimide markedly reduces plasma concentrations of medroxyprogesterone acetate and megestrol. Progesterone may enhance or reduce the anticoagulant effect of coumarins. Progesterone antagonises the anticoagulant effect of phenindione. Use of ulipristal acetate may result in reduced efficacy of progesterone. An adjustment in anti-diabetic dosage may be required. Breakthrough bleeding may occur when using terbinafine with progesterone. Progesterone may also affect the laboratory tests of hepatic and/or endocrine functions. **Pregnancy and lactation:** If pregnancy occurs during medication, Utrogestan 100mg should be withdrawn immediately. The data relating to inadvertent foetal exposure to combinations of estrogens + progesterone indicate no teratogenic or foetotoxic effect. Prescription of progesterone beyond the first trimester may reveal gravidic cholestasis. Utrogestan 100mg is not indicated during breast-feeding. Progesterone is distributed into breast milk. **Effects on ability to drive and use machines:** Utrogestan 100mg may cause drowsiness and/or dizziness; therefore care should be taken when driving or using machines. **Undesirable effects:** Frequency not known (cannot be estimated from the available data), from post-marketing experience primarily from oral administration of progesterone: abdominal pain, nausea, fatigue, headache, somnolence, dizziness, vaginal haemorrhage, pruritus. The following risks apply in relation to systemic oestrogen/progestogen treatment: breast cancer; endometrial cancer; ovarian cancer; venous thromboembolism; coronary artery disease; ischaemic stroke. Adverse reactions with systemic estrogen/progestogen treatment include: rash, urticaria, chloasma/melasma, pyrexia, insomnia, alopecia, irregular menstruation, amenorrhoea, breast pain/mastodynia, fluid retention/oedema, weight changes, changes in libido, depression, gall bladder disease, probable dementia in over 65 years of age, skin and subcutaneous disorders (erythema multiforme, erythema nodosum, vascular purpura). For further information on side effects and risk estimates please consult the SPC. **Overdose:** Symptoms may include drowsiness, somnolence, dizziness, or fatigue. Treatment of overdosage consists of discontinuation of Utrogestan together with institution of appropriate symptomatic and supportive care.

NHS Price: £6.60 for 30 capsules. **Legal category:** POM. **Marketing Authorisation Number:** PL 28397/0003. **Marketing Authorisation Holder:** Besins Healthcare, Rue Washington 80, 1050 Ixelles, Belgium. **Date of preparation of prescribing information:** March 2023 UTO/2023/001

Adverse events should be reported.
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Email: pharmacovigilance@besins-healthcare.com

Prescribing Information

Imvaggis (Estriol) 0.03 mg pessary

For full prescribing information, including side effects, precautions and contraindications, please consult the Summary of Product Characteristics (SPC).

Presentation: 1 pessary contains 0.03 mg estriol. Each pessary contains a maximum of 0.008 mg butylhydroxytoluene. **Indication:** Local treatment of vaginal symptoms of estrogen deficiency in postmenopausal women. **Posology and method of administration**: During the first 3 weeks of treatment, 1 pessary is administered daily. Thereafter, a maintenance dose of 1 pessary twice a week is recommended. For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used. For estrogen products for vaginal application of which the systemic exposure to the estrogen is very low, it is not recommended to add a progestogen. The pessary should be introduced deeply into the vagina, preferably in the evening before going to bed. **Contraindications:** Known, past or suspected breast cancer. Known or suspected estrogen-dependent malignant tumours (e. g. endometrial cancer). Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism). Known thrombophilic disorders (e. g. protein C, protein S, or antithrombin deficiency. Active or recent arterial thromboembolic disease (e.g., angina, myocardial infarction). Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal. Porphyria. Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. The risks and benefits should be reviewed annually, and HRT should only be continued as long as the benefit outweighs the risk. Imvaggis 0.03 mg pessary must not be combined with estrogen preparations for systemic treatment. Before initiating or reinstituting HRT a complete personal and family medical history should be taken. During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman. Women should be advised what changes in their breasts should be reported to their doctor or nurse. Vaginal infections should be treated with the appropriate medication before the start of treatment with Imvaggis 0.03 mg pessary. Patients should be closely supervised if any of the following conditions are present, have occurred previously and/or have been aggravated during pregnancy or previous hormone treatment. It should be taken into account that these conditions may recur or be aggravated during treatment with Imvaggis 0.03 mg pessary, in particular: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for estrogen-dependent tumours; hypertension; liver disorders; diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; history of endometrial hyperplasia; epilepsy; asthma and otosclerosis. Estriol should be discontinued if a contraindication is discovered or the following occur: jaundice or deterioration in liver function; significant increase in blood pressure; new onset of migraine-type headache; pregnancy. An increased risk of endometrial hyperplasia or uterine cancer has not been attributed to treatment with estriol by vaginal use. In women with an intact uterus the risk of endometrial hyperplasia and carcinoma is increased when systemic estrogens are administered alone for prolonged periods. Endometrial safety of long-term (>1 year) or repeated use of local vaginally administered estrogen is uncertain. Therefore, if repeated, treatment should be reviewed at least annually. If bleeding or spotting appears at any time on therapy, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy. The following risks have been associated with systemic HRT and apply to a lesser extent to estrogen products for vaginal application of which the systemic exposure to the estrogen is very low. However they should be considered in case of long term or repeated use of this product. Breast cancer, ovarian cancer, venous thromboembolism, coronary artery disease and ischaemic stroke. Estrogens may cause fluid retention and therefore patients with cardiac or renal dysfunction should be carefully observed. Women with pre-existing hypertriglyceridemia, should be followed closely during estrogen replacement or hormone replacement therapy, since rare cases of large increases of plasma triglycerides leading to pancreatitis have been reported with estrogen therapy in this condition.

Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. Estrogens increase thyroid binding globulin (TBG), leading to increased circulating total thyroid hormone. Other plasma proteins may be increased (angiotensinogen/renin substrate, alpha-I-antitrypsin, ceruloplasmin). Imvaggis 0.03 mg pessary cannot be used for contraception. The excipient butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. **Interactions:** Due to the vaginal administration and minimal systemic absorption, it is unlikely that any clinically relevant drug interactions will occur with Imvaggis 0.03 mg pessary. However, interactions with other locally applied vaginal treatments should be considered. If Imvaggis 0.03 mg pessary is used simultaneously with condoms made of latex it can decrease the tensile strength and thus impair the safety of condoms.

Pregnancy and lactation: The use of Imvaggis 0.03 mg pessary is not indicated during pregnancy. If pregnancy occurs during medication with the product, treatment should be withdrawn immediately. Given the high estriol concentrations in human pregnancy, any fetal exposure to estriol due to the use of low-dose pessaries is to be regarded as negligible. Imvaggis 0.03 mg pessary is not indicated during lactation. However, very low doses of vaginally applied estriol are unlikely to interfere with lactation.

Undesirable effects: At the beginning of treatment, when the vaginal epithelial layers are still atrophic, local irritation may occur as a sensation of heat, pain and/or itching. They are often transient and of mild intensity. The following undesirable effects commonly (>1/100; <1/10) occur: vulvovaginal burning, pruritus, pain and dysuria. The following are uncommon (≥1/1,000; <1/100): vaginal discharge, anorectal discomfort. Please refer to the SPC for the risks that have been associated with systemic HRT and apply to a lesser extent for estrogen products for vaginal application of which the systemic exposure to estrogen is very low. **Overdose:** Toxicity for estriol is very low. Overdose of Imvaggis 0.03 mg pessary by vaginal application is very unlikely. Symptoms that may occur in the case of a high dose accidentally ingested are nausea, vomiting and vaginal bleeding in females. There is no known antidote. If necessary, a symptomatic treatment should be instituted. **NHS Price:** 24 pessaries, £13.38. **Legal category:** POM. **Marketing Authorisation number:** PL 42714/0001. Marketing Authorisation Holder: Besins Healthcare (UK) Ltd, Lion Court, 25 Proctor Street, Holborn, London, WC1V 6NY, UK. **Date of preparation of Prescribing Information:** July 2022. IMV/2022/016

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