Prescribing Information Dimetrum® (dienogest)
2 mg Tablets

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

Presentation: 2 mg tablets containing 2 mg dienogest. Excipient with known effect: 62.81 mg lactose monohydrate. **Indication:** Treatment of endometriosis. **Method of administration:** Oral use. **Posology:** One tablet daily without any break, preferably at the same time each day with some liquid as needed. Can be taken with or without food. To be taken continuously without regard to vaginal bleeding and started on any day of the menstrual cycle. Stop any hormonal contraception prior to treatment initiation. Non-hormonal methods should be used if contraception required. If one or more tablets are missed, take one tablet, and then continue the next day. If tablet not absorbed due to vomiting of diarrhoea (within 3-4 hours after taking tablet), replace by one tablet. **Special Populations:** Not indicated in children prior to menarche. No relevant indication for use in the geriatric population. **Contraindications**: Do not use if the following conditions are present and discontinue immediately if conditions appear during treatment: active venous thromboembolic disorder, arterial and cardiovascular disease, past or present (e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease), diabetes mellitus with vascular involvement, presence or history of severe hepatic disease as long as liver function values have not returned to normal, presence or history of liver tumours (benign or malignant), known or suspected sex hormone-dependent malignancies, undiagnosed vaginal bleeding, hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions for use:** If the following conditions/risk factors are present or deteriorate during treatment an individual risk benefit analysis should be done before treatment is started or continued: serious uterine bleeding, changes in bleeding pattern, circulatory disorders (increased risk of venous thromboembolism, increased risk of stroke in patients with hypertension), tumours (risk of breast cancer, liver tumours), osteoporosis (decreased bone mineral density over 12 month treatment period), history of depression, development of sustained clinically significant hypertension, recurrence of cholestatic jaundice and/or pruritis which first occurred during pregnancy or use of sex steroids, effect on insulin resistance and glucose tolerance, diabetic women, especially those with a history of gestational diabetes mellitus, should be closely monitored, women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Dimetrum, history of extrauterine pregnancy or impairment of tube function, ovarian cysts. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. Discontinuation/withdrawal may be necessary, for further details refer to the SmPC. **Interactions**: Inducers or inhibitors of CYP3A4 may affect progestogen metabolism. Enzyme induction may reduce therapeutic effect and result in undesirable effects e.g. changes in uterine bleeding profile. Substances increasing clearance of sex hormones (diminished efficacy by enzyme induction) include phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin, ketoconazole and products containing St. John's wort (*Hypericum perforatum).* Many combinations of HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors (e.g. ritonavir, nevirapine, efavirenz), including combinations with HCV inhibitors can increase or decrease plasma concentrations of the progestin. Concomitant administration of strong/moderate CYP3A4 inhibitors can increase plasma concentrations of dienogest e.g. ketoconazole, erythromycin. **Fertility, pregnancy and lactation:** Must not be administered to pregnant women as treatment for endometriosis is not needed during pregnancy. Treatment during lactation is not recommended. Ovulation is inhibited during treatment in the majority of patients, however, Dimetrum is not a contraceptive, therefore non-hormonal contraception should be used if required. **Effects on ability to drive and use machines:** No effects on the ability to drive and use machines have been observed in users of products containing dienogest. **Undesirable effects:** The most frequently observed undesirable effects under treatment with 2 mg dienogest were: headache, breast discomfort, depressed mood and acne. Majority of patients experience changes in their menstrual bleeding pattern. Common: weight increase, depressed mood, sleep disorder, nervousness, loss of libido, altered mood, headache, migraine, nausea, abdominal pain, flatulence, abdominal distension, vomiting, acne, alopecia, back pain, breast discomfort, ovarian cyst, hot flushes, uterine/vaginal bleeding including spotting, asthenic conditions, irritability. Prescribers should consult the SmPC in relation to other adverse reactions. **Overdose:** Acute toxicity studies performed with dienogest did not indicate a risk of acute adverse effects in case of inadvertent intake of a multiple of the daily therapeutic dose. There is no specific antidote.

NHS Price: £20.50 per 28 tablets. **Legal category:** POM. **Marketing Authorisation Number:** PL 42714/0003. **Marketing Authorisation Holder** Besins Healthcare (UK) Limited, Lion Court, 25 Procter St, Holborn, London, WC1V 6NY United Kingdom. **Date of preparation of Prescribing Information:** August 2024 MAT-BHUK-DIEN-0005

Adverse events should be reported
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Besins Healthcare (UK) Ltd, Drug Safety on 0203 862 0920
Email: pharmacovigilance@besins-healthcare.com