Visanne® - Dienogest Tablets 2 mg. Qualitative and Quantitative Composition: Each uncoated tablet contains 2 mg Dienogest IP. Indication: For the management of pelvic pain associated with endometriosis. Dosage and method of administration: Method of administration: For oral use. Dosage regimen: Tablet-taking can be started on any day of the menstrual cycle. The dosage of Visanne is one tablet daily without any break, taken preferably at the same time each day with some liquid as needed. Tablets must be taken continuously without regard to vaginal bleeding. When a pack is finished the next one should be started without interruption. The efficacy of Visanne may be reduced in the event of missed tablets, vomiting and/or diarrhea (if occurring within 3-4 hours after tablet taking). In the event of missed tablet(s), the woman should take one tablet only, as soon as she remembers, and should then continue the next day to take the tablet at her usual time. A tablet not absorbed due to vomiting or diarrhea should likewise be replaced by one tablet. Please refer to the prescribing information for further details. Contraindications: Visanne should not be used in the presence of: active venous thromboembolic disorder, arterial and cardiovascular disease, present or in history (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 tumors (benign or malignant), known or suspected sex hormone-dependent malignancies, undiagnosed vaginal bleeding, hypersensitivity to the active substance or to any of the excipients. Should any of the conditions appear during the use of Visanne, treatment must be discontinued immediately. Special warnings and precautions for use: Before starting Visanne treatment, pregnancy must be excluded. Patients are advised to use non-hormonal methods of contraception (e.g. barrier method) if contraception is required. Pregnancies that occur among users of progestogen-only preparations used for contraception are more likely to be ectopic than are pregnancies among users of combined oral contraceptives. Therefore, in women with a history of extrauterine pregnancy or an impairment of tube function, the use of Visanne should be decided on only after carefully weighing the benefits against the risks. As Visanne is a progestogen-only preparation, it can be assumed that special warnings and special precautions for use of other progestogen-only preparations are also valid for the use of Visanne although not all of the warnings and precautions are based on respective findings in the clinical studies with Visanne. Please refer to the full prescribing information of Visanne® for further details. Interaction with other medicinal products and other forms of interaction: Progestins including Dienogest are metabolized mainly by the cytochrome P450 3A4 system (CYP3A4) located both in the intestinal mucosa and in the liver. Therefore, inducers or inhibitors of CYP3A4 may affect the progestogen drug metabolism. An increased clearance of sex hormones due to enzyme induction may reduce the therapeutic effect of Visanne and may result in undesirable effects e.g., changes in the uterine bleeding profile. A reduced clearance of sex hormones due to enzyme inhibition may increase the exposure to Dienogest and may result in undesirable effects. For a complete list of possible interactions, please refer to the prescribing information. Undesirable effects: Common undesirable effects > 1/100) are increased weight, depressed mood, sleep disorders, nervousness, loss of libido, mood altered, nausea, abdominal pain, increased weight, headache, depressed mood, mood alterations, breast pain and breast tenderness. Uncommon (> 1/1000 and < 1/100) include anaemia, weight decreased, increased appetite, anxiety, depression, autonomic nervous system imbalance. Please refer to the full prescribing information for a further details. For further prescribing information, please contact Bayer Zydus Pharma Private Limited, Bayer House, Central Avenue, Hiranandani Estate, Thane, Maharashtra, India Pin-400607. Email: medicalinfo.india@bayerzyduspharma.com. Source: Based on CCDS version 6 dated 13 May 2014; Rev: 17Aug 2015. Date of revision of text: 7th Sept 2017. For the use of a Registered Medical Practitioner Hospitals or Laboratory only.