ABBREVIATED PRESCRIBING INFORMATION*: VASFREE P

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Composition: It is available is available as 325 mg Paracetamol and 100 mg Flupirtine Maleate uncoated bilayer tablets. **Indication: VASFREE-P is** indicated for treatment of acute and chronic pain of moderate to severe intensity, i.e., for painful increased muscle tone of the posture and motor muscles, primary headache, tumour pain, dysmenorrhea and pain after traumatology/ orthopaedic operations and injuries. It is also useful in above painful conditions presenting along with fever. **Dosage and administration:** Adults-1 Tablet 3-4 times a day (Not exceeding 6 tablets in a day) The safety and efficacy of Flupirtine in children and adolescents have not been established. Product should not be used in children and adolescents under the age of 18 years. The duration of treatment must not exceed 2 weeks. **Contraindications: It is** contraindicated in cases with known hypersensitivity or idiosyncratic reaction to Paracetamol or Flupirtine. It should not be given to patients at risk of a hepatic encephalopathy nor to patients suffering from cholestasis since an encephalopathy or ataxia may develop or deteriorate. **Warnings and precautions:** It is recommended that initial doses of Flupirtine be reduced by 50% in patients with even mild degrees of renal impairment. When renal insufficiency is observed checking. lower doses of Flupirtine (50% of normal) be administered when initiating therapy in elderly patients. **Use in specific population:** No information concerning the effects of product on pregnant women is available. If there are compelling reasons for giving product to a woman, breast-feeding should be stopped. It should not be given to patients at risk of a hepatic encephalopathy nor to patients suffering from cholestasis since an encephalopathy or ataxia may develop or deteriorate. **Drug Interactions:** Flupirtine may interact with anticoagulants such as warfarin. Alcohol or other sedatives such as benzodiazepines can increase the tiredness and dizziness may be experienced with flupirtine use. The speed of absorption of Paracetamol is reduced by cholestyramine and therefore the cholestyramine should not be taken within one hour if maximal analgesia is required. The absorption of Paracetamol is increased by metoclopramide and domperidone and hence concurrent use need not be avoided. The anticoagulant effect of warfarin and other coumarin anticoagulant may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding. **Adverse drug reactions**: Most of the adverse effects depended on the dose. In many cases they disappeared in the course of treatment or were reversible after the end of the therapy. Very frequent side effects (> 10 %): Tiredness (about 15 % of patients), especially at the start of treatment Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia purpura, methaemoglobenaemia. **Storage:** Store below 30°C. Protect from light and moisture. Keep out of reach of children. . This is abbreviated prescribing information. For detailed information please refer to full prescribing information or contact us. (Updated on November 2023)