Filnarine (Morphine Sulphate) SR 10 mg, 30 mg, 60 mg and 100 mg, and 200 mg Prolonged Release Film-coated tablets Abbreviated Prescribing Information

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Presentation: Each tablet contains 10 mg, 30 mg, 60 mg or 100 mg, or 200 mg of morphine sulphate. **Indications:** Treatment of severe pain, particularly cancer pain and post-operative pain. **Dosage and administration:** For oral administration. The tablets should be swallowed completely with some liquid and must not be divided or dissolved before administration. **Adults and adolescents (≥12 years):** Started on 10-30 mg 12-hourly for severe pain following initiation of treatment with immediate release morphine. Patients with severe pain uncontrolled by weaker opioids should be started on 30 mg 12-hourly. A starting dose as low as 10 mg 12-hourly may be appropriate for the elderly who may be susceptible to morphine, patients with low body-weight, in hypothyroidism, and in patients with significantly impaired renal or hepatic function. Increased severity of pain will require an increased dosage. An incremental increase of 30%-50% in the daily dose may be appropriate. **Children (6 years and older):** A starting dose in the range of 0.2 mg- 0.8 mg morphine/kg 12-hourly with dose titration as for adults is recommended. If it is not possible to give the recommended dosage with this formulation another formulation should be chosen. Filnarine SR tablets are not recommended in the first 24 hours post operatively or until normal bowel function has returned. Thereafter it is suggested that the following dosage schedule be observed at the physician's discretion: 20 mg 12 hourly to patients under 70kg, 30 mg 12 hourly to patients over 70kg. A reduction in dosage may be advisable and is not recommended in children for post operative pain. **Contraindications:** Hypersensitivity to morphine or any of the excipients, children under 6 years of age, respiratory depression, airway obstruction caused by mucus, obstructive airways disease, convulsive disease, head injury, raised intracranial pressure, paralytic ileus, "acute abdomen", delayed gastric emptying, acute hepatic disease, post-operative after biliary surgery, 24 hours before cordotomy, concurrent administration of monoamine oxidase inhibitors or within two weeks of discontinuation of their use, concomitant use of morphine agonist/antagonist, and agitation states in patients affected by alcohol or hypnotics. **Precautions and warnings:** Use with caution in opiate-dependant patients and in patients with hypotension with hypovolaemia, disorders of consciousness, disease of the biliary tract, biliary or urinary colic, pancreatitis, obstructive and inflammatory bowel disorders, prostatic hypertrophy and adrenocortical insufficiency. Pre-operative administration is not recommended. Should be used with caution post operatively and following abdominal surgery. Abrupt withdrawal after long term treatment may lead to a withdrawal syndrome within a few hours. There is cross tolerance with other opioids. This product contains lactose and should not be administered to patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption. **Interactions:** Patients must not consume alcohol beverages or use prescription or non-prescription medications containing alcohol while on morphine sulphate therapy as it may result in the rapid release and absorption of a potentially fatal dose of morphine. Morphine potentiates the effect of tranquilisers, anaesthetics, hypnotics, sedatives, alcohol, muscle relaxants, and antihypertensives. Cimetidine inhibits the metabolism of morphine. Monaoamine oxidase inhibitors are known to interact with narcotic analgesics producing CNS excitation or depression with hyper-or hypotensive crisis. Rifampicin induces the metabolism of orally administered morphine to a high degree and therefore higher doses may be needed. Clomipramine and amitriptyline increase the analgesic effects of morphine, which may partly be due to an increased bioavailability. An adjustment of the dose may be necessary. Combination with morphine agonists/antagonists (buprenorphine, nalbuphine, pentazocine) is contraindicated because there is reduction of the analgesic effect by competitive blocking of the receptors, with a risk of occurrence of withdrawal syndrome. **Pregnancy and lactation:** Morphine is not recommended during pregnancy, labour or breast-feeding. Morphine sulphate should be used during pregnancy only when the potential benefits justify the possible risks to the foetus. **Effects on ability to drive and use machines:** May reduce attention and reaction time. This should be expected particularly at the start of treatment and when dosage is increased or when associated with concomitant alcohol or other sedative medicines. **Adverse reactions:** Anaphylactic and anaphylactoid reactions, palpitations, bradycardia, tachycardia, raised intracranial pressure, respiratory depression and bronchospasm. *Common:* Drowsiness, miosis, nausea, vomiting and constipation. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** Signs of morphine toxicity and overdose are pin-point pupils, respiratory depression, and hypotension. Circulatory failure and deepening coma may occur in more severe cases. In addition tachycardia, vertigo, dropping of body temperature, relaxation of skeletal muscles; in children general convulsions were observed. Primary attention should be given to the establishment of a patent airway and institution of assisted or controlled ventilation. **Price:** Packs of 60, 10 mg tablets £3.30, 30 mg tablets £7.89, 60 mg tablets £15.39, 100 mg tablets £21.79, and 200 mg tablets £43.59. **Legal category:** CD (Schedule 2) POM. **Marketing Authorisation Number:** 10mg, 30 mg, 60 mg, and 100 mg: 00289/0382-5. Filnarine SR 200mg: 00289/1019. **Marketing Authorisation Holder:** Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom. **Job Code:** UK/MED/14/0069. **Date of Preparation:** June 2014.