**Prescribing Information for Angitil (Diltiazem hydrochloride) SR 90mg, 120mg and 180mg and Angitil XL 240mg and 300mg capsules**

**See Summary of Product Characteristics (SPC) before prescribing.**

**Presentation:** Available in a range of doses. Prolonged release capsules containing 90mg, 120mg, 180 mg, 240 mg or 300 mg diltiazem hydrochloride. **Indications:** For the management of angina pectoris. For management of mild to moderate hypertension. **Dosage:** **Refer to SPC for details and recommendations.** For oral use, with or without food. The capsules should be swallowed whole and not chewed. Angitil SR capsules are taken twice daily and Angitil XL capsules are taken once daily. *Adults:* The usual initial dose is 90 mg twice daily, to be increased gradually to 120 or 180 mg twice daily if required. Patients currently receiving a total daily dose of 180 mg diltiazem (as 90mg *bd*) may be titrated up to 240 mg (*od*), and patients receiving 240 mg diltiazem (as 120mg *bd*) should commence treatment on the 240 mg capsule (*od*), titrating to 300 mg (*od*) when necessary. *Elderly and patients with impaired renal or hepatic dysfunction:* Starting dose should be 60 mg twice daily. Dose may be increased gradually, but careful monitoring is advised. *Paediatric population:* Not recommended. **Contra-indications:** Hypersensitivity to diltiazem or to any of the excipients. Sick sinus syndrome, 2nd or 3rd degree atrioventricular (AV) block in patients without a functioning pacemaker. Severe bradycardia (less than 50 bpm). Left ventricular failure with pulmonary stasis. Decompensated cardiac failure. Lactation. Concurrent use with dantrolene infusion. Combination with ivabradine. **Warnings and precautions:** Closely monitor patients with reduced left ventricular function, bradycardia or with a 1st degree AV block or prolonged PR interval on the electrocardiogram (risk of exacerbation and rarely, of complete block). Increase of plasma concentrations of diltiazem may be observed in the elderly and patients with renal or hepatic insufficiency. In the case of general anaesthesia, the anaesthetist must be informed that the patient is taking diltiazem. Treatment with diltiazem may be associated with mood changes, including depression. In such cases, drug discontinuation should be considered. Use with caution in patients at risk of developing an intestinal obstruction, as diltiazem has an inhibitory effect on intestinal motility. Carefully monitor patients with latent or manifest diabetes mellitus due to a possible increase in blood glucose. The use of diltiazem may induce bronchospasm, including asthma aggravation, especially in patients with pre-existing bronchial hyper-reactivity. Monitor patients for signs and symptoms of respiratory impairment. Diltiazem is considered unsafe in patients with acute porphyria. Residues from slow release formulations of the product may pass into the patient’s stools. **Interactions: Refer to SPC for full information.***Combinations contraindicated for safety reasons*: Dantrolene (infusion); Ivabradine. *Combinations requiring caution*: Alpha-antagonists; beta-blockers; amiodarone, digoxin; antiarrhythmic agents; nitrate derivatives; ciclosporin; phenytoin; x-ray contrast media; carbamazepine; theophylline; anti-H­2 agents (cimetidine and ranitidine); rifampicin; lithium; antiplatelet drugs. *Combinations to be taken into account*: Diltiazem is metabolised by CYP3A4. A moderate (less than 2-fold) increase of diltiazem plasma concentration in cases of co-administration with a stronger CYP3A4 inhibitor has been documented. Grapefruit juice may increase diltiazem exposure; therefore, grapefruit juice should be avoided if an interaction is suspected. Diltiazem is also a CYP3A4 isoform inhibitor. Co-administration with other CYP3A4 substrates may result in an increase in plasma concentration of either co-administered drug. Co-administration of diltiazem with a CYP3A4 inducer may result in a decrease of diltiazem plasma concentrations. Statins; cilostazol; benzodiazepines (midazolam, triazolam); corticosteroids (methylprednisolone). *General information to be taken into account:* Caution and careful titration are necessary in patients receiving diltiazem concomitantly with other agents known to affect cardiac contractility and or/ conduction due to the potential for additive effects. Angitil should not be taken at the same time as alcohol, as it may increase dose-dependent effects and lead to potential adverse pharmacodynamic interactions. **Effects on ability to drive and use machines:** On the basis of reported adverse drug reactions, i.e. dizziness (common), malaise (common), the ability to drive and use machines could be altered. However, no studies have been performed. **Pregnancy and lactation:** *Pregnancy:* Not recommended, as well as in women of child-bearing potential not using effective contraception. *Breast feeding:* As this drug is excreted in breast milk, breast feeding is contraindicated. **Side effects: Refer to SmPC for full list.** Very common (≥1/10): Peripheral oedema. Common (≥1/100 to <1/10): Atrio-ventricular block (may be of first, second or third degree; bundle branch block may occur); palpitations; flushing; constipation; dyspepsia; gastric pain; nausea; erythema; headache; dizziness; malaise. **Overdose:** See SPC for management guidance. **Marketing Authorisation Numbers and Basic NHS Price:** SR capsules are sold in a pack size of 56 and XL capsules are sold in a pack size of 28. Angitil SR 90 mg PL 06934/0195 - £7.03; Angitil SR 120 mg PL 06934/0196 - £6.91; Angitil SR 180 mg PL 06934/0197 - £13.27; Angitil XL 240 mg PL 06934/0198 - £7.94; Angitil XL 300 mg PL 06934/0199 - £6.98. **Product License Holder:** Ethypharm, 194 Bureaux de la Colline – Bâtiment D, 92213 Saint-Cloud Cedex, France. **Legal Category:** POM. **Date of Preparation:** December 2019.

**Adverse events should be reported. Reporting forms and information can be found at** [**www.mhra.gov.uk/yellowcard**](http://www.mhra.gov.uk/yellowcard)**. Adverse events should also be reported to Martindale Pharma, an Ethypharm Group Company. Tel: 01277 266 600. e-mail: drugsafety.uk@ethypharm.com**