Ventavis® (iloprost (as iloprost trometamol) 10 microgram/ml nebuliser solution & Ventavis 20 microgram/ml nebuliser solution iloprost)
Prescribing Information

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: *Ventavis® 10 microgram/ml nebuliser solution:* 1 ml solution contains 10 microgram iloprost (as iloprost trometamol). *Ventavis 20 microgram/ml nebuliser solution:* 1 ml solution contains 20 microgram iloprost (as iloprost trometamol). **Indication:** Treatment of adult patients with primary pulmonary hypertension (PPH), classified as NYHA functional class III, to improve exercise capacity and symptoms. **Posology & method of administration:** Only for use by a physician experienced in the treatment of Pulmonary Hypertension (PH). For inhalation via nebuliser, 2.5 or 5 microgram iloprost (as delivered at the mouthpiece of the nebuliser) 6 to 9 times per day according to individual need and tolerability. Start with the low dose of 2.5 microgram for the first inhalation. If this dose is well tolerated, dosing should be increased to 5 microgram iloprost and maintained at that dose. In case of poor tolerability of the 5 microgram dose, the dose should be reduced to 2.5 microgram. *Duration of treatment:* Depends on clinical status and is left to the physician's discretion. *Hepatic Impairment:* Special caution has to be exercised. Initially doses of 2.5 microgram should be administered using Ventavis 10 microgram/ml with a maximum dosing interval of 3-4 hours. *Renal impairment:* No dose adjustment in patients with creatinine clearance > 30 ml/min. In patients with renal failure requiring dialysis, elimination is reduced so apply the same dosing recommendations as quoted for patients with hepatic impairment. *Paediatric population:* No data from controlled clinical trials are available. **Contraindications:** Hypersensitivity to iloprost or any excipients. Conditions where effects of Ventavis on platelets may increase risk of haemorrhage. Severe coronary heart disease, unstable angina, Myocardial infarction (MI) within the last six months, decompensated cardiac failure if not under close medical supervision, severe arrhythmias. Cerebrovascular events within the last 3 months. PH due to venous occlusive disease. Congenital or acquired valvular defects with clinically relevant myocardial function disorders not related to PH. **Warnings and precautions:** Not recommended in patients with unstable PH with advanced right heart failure. Check blood pressure when initiating Ventavis & take care to avoid further hypotension in patients with postural hypotension or receiving treatment known to reduce blood pressure. Do not initiate Ventavis if systolic blood pressure is <85mmHg. Pulmonary vasodilatory effect of Ventavis is of short duration (1 to 2 hours). Avoid exceptional straining, e.g. during physical exercise, in patients with syncope and PH. Consider inhalation before physical exertion. Re-evaluate therapy if syncope occurs. Ventavis inhalation might entail the risk of inducing bronchospasm, especially in patients with bronchial hyperactivity. Benefits not established in patients with chronic obstructive pulmonary disease (COPD) & severe asthma. Monitor carefully patients with concomitant acute pulmonary infections, COPD or severe asthma. Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). If signs of pulmonary oedema occur, consider associated PVOD, and stop therapy. Monitor carefully if therapy is stopped or interrupted as rebound effect not excluded. Consider alternative treatment in critically ill patients. Titrate dose cautiously with 3-4 hour dose interval in patients with hepatic dysfunction or renal failure with dialysis. Pre-clinical data in dogs shows slight rise in fasted serum glucose levels with oral iloprost for up to 1 year, relevance to Ventavis in humans uncertain. To minimise accidental exposure use Ventavis with inhalation- triggered nebulisers and keep room well ventilated. Newborns, infants and pregnant women should not be subjected to Ventavis in the room air. Use mouthpiece not face mask. Avoid oral ingestion & contact with skin or eyes. Ventavis contains small amounts (0.81 mg/ml) of ethanol (alcohol). **Interactions:** May potentiate vasodilators and antihypertensives & thus increase risk of hypotension. Ventavis inhibits platelet function; bleeding risk may increase with concomitant anticoagulants or platelet aggregation inhibitors. Monitor carefully. **Fertility, pregnancy & lactation:** Women of childbearing potential should use effective contraceptive measures during treatment. Avoid pregnancy as it may lead to life-threatening exacerbation of the disease. Limited data in pregnant women. Use may be considered taking into account benefit/risk assessment. It is not known whether Ventavis is excreted in human milk so use should be avoided if breastfeeding. Animal studies have not shown harmful effect of iloprost on fertility. Prescribers should consult the SmPC for full information. **Effects on ability to drive and use machines:** Ventavis has major influence on the ability to drive and use machines for patients experiencing hypotensive symptoms (e.g. dizziness). **Undesirable effects:** ***Very common*** **–** bleeding events (inc. cerebral and intracranial haemorrhage)*, headache, vasodilatation, flushing, chest discomfort or pain, cough, nausea, pain in jaw/trismus, peripheral oedema.

Common – dizziness, tachycardia, palpitations, syncope, hypotension*, dyspnoea, pharyngolaryngeal pain, throat/mouth/tongue irritation or pain, diarrhoea, vomiting, rash. ***Serious side effects: cf CI/W&P – in addition:*** thrombocytopenia, hypersensitivity, bronchospasm*. Syncope & peripheral oedema are symptoms of the disease itself but may also occur under therapy. **Most serious ADRs, for which life-threatening &/or fatal cases have been reported*. Prescribers should consult the SmPC in relation to other side effect information. **Overdose:** Symptoms of overdose are mainly related to the vasodilatory effect. Frequently observed symptoms following overdose are dizziness, headache, flushing, nausea, jaw pain or back pain. Hypotension, an increase of blood pressure, bradycardia or tachycardia, vomiting, diarrhoea and limb pain might also be possible. No specific antidote is known. Interruption of the inhalation session, monitoring & symptomatic measures are recommended. **Incompatibilities:** Do not mix with other medicinal products. **Legal category:** POM. **Package Quantities and Basic NHS Costs:** *Ventavis® 10 microgram/ml nebuliser solution:* 1 ml nebuliser solution. 42 ampoule pack £560.27, 168 ampoule pack £2241.08, 168 ampoules co-packed with Breelib Monthly Pack** £2241.08; *Ventavis® 20 microgram/ml nebuliser solution:* 1 ml nebuliser solution. 42 ampoule pack £560.27, 168 ampoules co-packed with Breelib Monthly Pack** £2241.08. *** Breelib monthly consumables containing 1 mouthpiece and 1 nebuliser unit.* **Marketing Authorisation Numbers**: *Great Britain* - PLGB 00010/0703 (Ventavis 10 microgram/ml), PLGB 00010/0704 (Ventavis 20 microgram/ml); *Northern Ireland* - EU/1/03/255/011, 013 (Ventavis 10 microgram/ml), EU/1/03/255/012, 014 (Ventavis 20 microgram/ml). **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD Telephone: 0118 2063000. **Date of preparation:** September 2022.

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 Bayer plc. Tel.: 0118 2063500, Fax.: 0118 2063703, Email: pvuk@bayer.com