PRESCRIBING INFORMATION

BELNIFREM (Cytisinicline) 1.5 mg film-coated tablets

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication: Smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking. The treatment goal of BELNIFREM is the permanent cessation of the nicotine containing products use.

Presentation: Round, biconvex, light green or greenish film-coated tablets of 5mm diameter.

Dosage and administration: One package of BELNIFREM (100 tablets) is sufficient for a complete treatment course. The duration of therapy is 25 days. BELNIFREM should be taken according to the following schedule:

- From the 1st to the 3rd day 1 tablet should be taken every 2 hours (6 tablets daily)
- From the 4th to the 12th day 1 tablet should be taken every 2.5 hours (5 tablets daily)
- From the 13th to the 16th day 1 tablet should be taken every 3 hours (4 tablets daily)
- From the 17th to the 20th day 1 tablet should be taken every 5 hours (3 tablets daily)
- From the 21st to the 25th day 1 to 2 tablets daily should be taken

Smoking should be stopped no later than on the 5th day of treatment. Smoking should not be continued during treatment as this may aggravate adverse reactions (see section 4.4 of SmPC or section Warnings and precautions below). In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months.

Method of administration: BELNIFREM should be taken orally with a suitable amount of water.

Special Population (renal impairment, hepatic impairment): The drug product is not recommended for use in this patient population.

Elderly Population: Due to limited clinical experience, BELNIFREM is not recommended for use in elderly patients over 65 years of age.

Paediatric Population: BELNIFREM is not recommended for use in persons under 18 years of age.

Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of SmPC, unstable angina, a history of recent myocardial infarction, clinically significant arrhythmias, a history of recent stroke, pregnancy and breastfeeding.

Warnings and precautions: BELNIFREM should be taken only by those with a serious intention of weaning off nicotine. Patient should be aware, that the simultaneous administration of the drug and smoking or use of products containing nicotine could lead to aggravated adverse reactions of nicotine. BELNIFREM should be taken with caution in case of ischemic heart disease, heart failure, hypertension, pheochromocytoma, atherosclerosis and other peripheral vascular diseases, gastric and duodenal ulcer, gastroesophageal reflux disease, hyperthyroidism, diabetes and schizophrenia.

Stopping Smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is

of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole. The plasma concentration of other medicinal products metabolised in part by CYP1A2 e.g. imipramine, olanzapine, clomipramine and fluvoxamine may also increase on cessation of smoking, although data to support this are lacking and the possible clinical significance of this effect for these drugs is unknown. Limited data indicate that the metabolism of flecainide and pentazocine may also be induced by smoking.

Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment.

History of psychiatric disorders: Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly.

Aspartame: The tablets contain aspartame. Aspartame is a source of phenylalanine. It may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Interactions with other medicinal products: BELNIFREM should not be used with anti-tuberculosis drugs. No other clinical data on significant interaction with other drugs. Patient should be aware, that the simultaneous administration of the drug and smoking or use of products containing nicotine could lead to aggravated adverse reactions of nicotine (see section 4.4 of SmPC or section Warnings and precautions above).

Fertility, pregnancy and lactation:

Pregnancy: There are no or limited amount of data from the use of cytisine in pregnant women. BELNIFREM is contraindicated during pregnancy (see section 4.3 of SmPC).

Breastfeeding: BELNIFREM is contraindicated during breast-feeding (see section 4.3 of SmPC).

Fertility: No data on the effects of BELNIFREM on fertility.

Women of childbearing potential: Women of childbearing potential must use highly effective contraception while taking BELNIFREM (see section 4.5 and 4.4 of SmPC). Women using systemically acting hormonal contraceptives should add a second barrier method.

Effects on ability to drive and use machines: BELNIFREM has no influence on the ability to drive and use machines.

Undesirable effects:

Very Common (≥1/10): Change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, tachycardia, hypertension, dry mouth, diarrhea, nausea, changes in flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen), rash, myalgia and fatigue

Common (≥1/100 to < 1/10): Difficulty in concentration, slow heart rate, abdominal distension, burning tongue and malaise

Uncommon (≥1/1,000 to < 1/100): Feeling of heaviness in the head, decreased libido, lacrimation, dyspnea, increased sputum, excessive salivation, sweating, decreased elasticity of the skin, tiredness and increase in serum transaminase levels

For rare and very rare undesirable effects, please refer to the SmPC.

Legal Category: POM **Marketing Authorisation Number**: PL 32556/0024 **MAH**: Adamed Pharma S.A., Pieńków, ul. M. Adamkiewicza 6A, 05-152 Czosnów, Poland **NHS Price**: 115.00 GBP **Date of Revision of Prescribing Information**: May 2025, UK-BLN-2025-00012

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Adverse events should be reported

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via the Yellow Card website http://www.mhra.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store or some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals. Alternatively, you can report suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. When reporting please provide as much information as possible. By reporting adverse drug reactions you can help provide more information on the safety of this medicine. You can also report directly to the distributor at pv.uk@viatris.com