Venclyxto 10 mg/50 mg/100 mg film-coated tablets

▼ This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.

Name of the Medicinal Product: Venclyxto 10 mg/50 mg/100 mg film-coated tablets

Active Ingredients: Venetoclax

Composition: Each film-coated tablet contains 10 mg/50 mg/100 mg of venetoclax.

Excipients: Tablet core: Copovidone (K 28), Colloidal anhydrous silica (E551), Polysorbate 80 (E433), Sodium stearyl fumarate, Anhydrous calcium hydrogen phosphate (E341 (ii)); coating 10 mg/100 mg: Iron oxide yellow (E172), Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol 3350 (E1521), Talc (E553b); coating 50 mg: Iron oxide yellow (E172), Iron oxide red (E172), Iron oxide black (E172), Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol 3350 (E1521), Talc (E553b)

Therapeutic indications: Venclyxto in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). Venclyxto in combination with rituximab is indicated for the treatment of adult patients with CLL who have received at least one prior therapy. Venclyxto monotherapy is indicated for the treatment of CLL in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor, or in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Concomitant use of strong CYP3A inhibitors at initiation and during the dose-titration phase. Concomitant use of preparations containing St. John's wort.

Adverse Drug Reactions: *very common:* pneumonia, upper respiratory tract infection, neutropenia, anaemia, lymphopenia, hyperkalaemia, hyperphosphataemia, hypocalcaemia, diarrhoea, vomiting, nausea, constipation, fatigue, *common:* sepsis, urinary tract infection, febrile neutropenia, tumour lysis syndrome, hyperuricaemia, blood creatinine increased.

Prescription only. Version: April 2020, **Marketing Authorisation Holder:** AbbVie Deutschland GmbH & Co. KG, Knollstraße, 67061 Ludwigshafen, Germany