

**RESTRICTED**

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency of Turkey

Number : 62820468-000-E.90433 Subject : Products containing the active substance "Bendamustine"

NORMAL 31.05.2019 DOSSIER

Ref: Our announcement to associations, dated 10.12.2018, with No. E.212517

Our announcement to associations on products with the active substance bendamustine has been annulled and the Summary of Product Characteristics (SPCs) and Package Leaflet (PL) of the products containing the referred active substance should be arranged as follows:

Summary of Product Characteristics: 4.1. Therapeutic indications It should be used alone or in combination with rituximab in newly diagnosed or relapse/refractory chronic lymphocytic leukemia patients with 17p deletion or negative TP53 mutation who are not suitable for fludarabine-based treatment due to their comorbidities.

It should be used in combination with prednisolone in the treatment of ISS stage III multiple myeloma subjects aged above 65 years who are not suitable for autologous stem cell transplantation and cannot receive bortezomib or thalidomide-containing regimens due to neuropathy.

It is indicated in the treatment of indolent non-Hodgkin's lymphoma subjects who have progressed during or within the first 6 months of treatments containing rituximab.

Package Leaflet: How to take X? It should be administered alone or together with rituximab (a medicine used in the treatment of B-cell lymphoma) in patients diagnosed with chronic lymphocytic leukemia (a slowly progressing cancer type), who have 17p deletion or negative TP53 mutation (a type of genetic disorder with negative impact on treatment response) and are not suitable for fludarabine (a medicine used in the treatment of cancer) based treatment due to their concomitant diseases.

It should be administered together with prednisolone (a type of corticosteroid) in the treatment of advanced stage multiple myeloma (a type of bone marrow cancer) subjects aged above 65 years who are not suitable for autologous stem cell transplantation and cannot receive regimens containing bortezomib or thalidomide (two separate cancer medicines with the potential to damage nerves) due to neuropathy.

It should be used as monotherapy or together with rituximab in the treatment of non-Hodgkin's lymphoma subjects who have progressed during or within the first 6 months of treatments containing rituximab.

I hereby submit for your information and kindly request that any views, proposal and additions regarding this decision are submitted to the Clinical Evaluation Unit until 18.07.2019, and that no

application is made to the Pharmacological Evaluation Unit regarding "Bendamustine" during the referred process. Dr. Pharm. Nihan Burul BOZKURT on behalf of the President of the Agency Deputy Head of Department

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association