

RESTRICTED

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

Number : 62820468-000-E.153732 Subject : Products Containing the Active Substance
Bendamustine

NORMAL 03.10.2019

DOSSIER

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

Our announcement to associations regarding the products with the active substance bendamustine has been annulled and it is necessary to arrange as follows the Summary of Product Characteristics (SPC) and Package Leaflet (PL) of the products containing the referred active substance:

Summary of Product Characteristics: 4.1 Therapeutic indications It should be used as monotherapy or in combination with rituximab in newly diagnosed or relapse/refractory chronic lymphocytic leukemia patients who have a negative 17p deletion or TP53 mutation and are not eligible for fludarabine-based therapy due to their comorbidities. It should be used in combination with prednisolone in the treatment of ISS stage III multiple myeloma subjects who are older than 65, are not eligible for autologous stem cell transplantation and cannot receive regimens containing bortezomib or thalidomide due to neuropathy. It is indicated for monotherapy or combination with rituximab during treatments containing rituximab or in the treatment of indolent non-Hodgkin's lymphoma subjects who progress within the first 6 months. Package Leaflet: How to use x It should be used as monotherapy or in combination with rituximab (a medicine used in the treatment of B cell lymphoma) in patients diagnosed with chronic lymphocytic leukemia (a type of slow-growing cancer), who have a negative 17p deletion or TP53 mutation (a type of genetic disorder impacting negatively the response to treatment) due to their concomitant diseases and who are not eligible for a fludarabine-based treatment (a medicine used in cancer treatment). It should be administered in combination with prednisolone (a type of corticosteroid) in the treatment of subjects with advanced stage multiple myeloma (a type of bone marrow cancer) who are older than 65, are not eligible for autologous (self) stem cell transplant and cannot receive regimens containing bortezomib or thalidomide (two different cancer medicines with the potential to cause nerve damage) due to neuropathy.

It is indicated for monotherapy or combination with rituximab during treatments containing rituximab or in the treatment of slow-growing non-Hodgkin's lymphoma subjects who progress within the first 6 months. I hereby submit for your information and kindly request that SPC/PL applications relating to the products in which abovementioned amendments are made are submitted to the Pharmacological Evaluation Unit until 04.11.2019 for review.

Dr. Hakkı GÜRSÖZ President of the Agency 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