

Recommendations on extensions of therapeutic indication:

Byfavo (remimazolam): extension of indication to the induction and maintenance of general anesthesia in adults. Byfavo was already authorised for procedural sedation in adults.

Dupixent (dupilumab): extension of indication to the treatment of severe atopic dermatitis (AD) in children 6 months to 11 years old who are candidates for systemic therapy. Dupixent was already authorised in children 6 to 11 years old in this setting and in adults and adolescents older than 12 year for the treatment of moderate-to-severe AD. Furthermore, Dupixent was already authorised for the treatment of asthma, chronic rhinosinusitis with nasal polyposis and prurigo nodularis.

Nubeqa (darolutamide): extension of indication to the treatment of adult men with metastatic hormone sensitive prostate cancer in combination with docetaxel and androgen deprivation therapy. Nubeqa was already authorised for the treatment of non-metastatic castration resistant prostate cancer.

Reblozyl (luspatercept): extension of indication to the treatment of anaemia associated with non-transfusion-dependent beta-thalassaemia in adults. Reblozyl was already authorised for the treatment of anaemia associated with transfusion-dependent beta-thalassaemia.

Trecondi (treosulfan): extension of indication to include the conditioning treatment prior to allogeneic haematopoietic stem cell transplantation in paediatric patients older than one month with non-malignant diseases, in combination with fludarabine. Trecondi was already authorised for conditioning treatment in adults with malignant and non-malignant diseases and in paediatric patients with malignant diseases.

Trulicity (dulaglutide): extension of indication to the treatment of patients 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.

Trulicity was already authorised in adults in this indication.

Wakix (pitolisant): extension of indication to the treatment of narcolepsy with or without cataplexy in adolescents and children from the age of 6 years. Wakix was already authorised in adults in this indication.