

Conditions for approval "without a prescription, in a pharmacy" of a medicinal products containing flurbiprofen (ATC code R02AX01)

(Version 1.0, November 21st 2025)

Medicinal products from the pharmacotherapeutic group of throat preparations, other throat preparations containing the active substance flurbiprofen (ATC code: R02AX01) are approved with the prescription and distribution status "without a prescription, in a pharmacy", if they meet the following conditions:

Pharmaceutical form	Lozenge Oromucosal spray, solution
Route of administration	Oromucosal
Maximum allowed strength	8,75 mg
Therapeutic indications	For short-term symptomatic relief of sore throat
Target population	Adults and adolescents over 12 years of age
Recommended daily dose	<u>Lozenge</u> 5 lozenge <u>Oromucosal spray, solution</u> 5 doses (1 dose = 3 acuations)
Duration of treatment	For short-term use up to 3 days
Maximum acceptable package size	<u>Lozenge</u> 16 lozenges <u>Oromucosal spray, solution</u> 15 ml solution
Distribution	Supply through pharmacies
Advertising to general public	Allowed