

**Summary of European Union decisions on marketing authorisations in respect of medicinal products  
from 1 August 2020 to 31 August 2020**

*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC<sup>(1)</sup> or Article 38 of Directive 2001/82/EC<sup>(2)</sup>)*

(2020/C 318/02)

**— Refusal of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
19.8.2020	Budesonide SUN and associated names	budesonide	See Annex	See Annex	20.8.2020

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<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 1.

## ANNEX

## List of medicinal products and presentations

Member State EU/ EEA	Applicant	Invented Name	Strength	Pharmaceutical form	Route of administration
Germany	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	0,25 mg	nebuliser suspension	Inhalation use
Germany	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	0,5 mg	nebuliser suspension	Inhalation use
Germany	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	1 mg	nebuliser suspension	Inhalation use
Italy	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	0,125 mg/ml	nebuliser suspension	Inhalation use
Italy	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	0,25 mg/ml	nebuliser suspension	Inhalation use
Italy	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	0,5 mg/ml	nebuliser suspension	Inhalation use
The Netherlands	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	250 microgram/2 ml	nebuliser suspension	Inhalation use
The Netherlands	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	500 microgram /2 ml	nebuliser suspension	Inhalation use

Member State EU/ EEA	Applicant	Invented Name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide SUN	1 000 microgram/2 ml	nebuliser suspension	Inhalation use
Poland	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budezonid SUN	0,125 mg/ml	nebuliser suspension	Inhalation use
Poland	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budezonid SUN	0,25 mg/ml	nebuliser suspension	Inhalation use
Poland	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budezonid SUN	0,5 mg/ml	nebuliser suspension	Inhalation use
Spain	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesónida SUN	0,25 mg/ml	nebuliser suspension	Inhalation use
Spain	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesónida SUN	0,5 mg/ml	nebuliser suspension	Inhalation use
Sweden	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	0,125 mg/ml	nebuliser suspension	Inhalation use
Sweden	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	0,25 mg/ml	nebuliser suspension	Inhalation use

Member State EU/ EEA	Applicant	Invented Name	Strength	Pharmaceutical form	Route of administration
Sweden	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonid SUN	0,5 mg/ml	nebuliser suspension	Inhalation use
United Kingdom	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide	0,125 mg/ml	nebuliser suspension	Inhalation use
United Kingdom	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide	0,25 mg/ml	nebuliser suspension	Inhalation use
United Kingdom	Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87 2132 JH Hoofddorp The Netherlands	Budesonide	0,5 mg/ml	nebuliser suspension	Inhalation use