

DODATEK I

**SEZNAM IMEN, FARMACEVTSKIH OBLIK, JAKOSTI ZDRAVILA, POTI UPORABE
ZDRAVILA, PREDLAGATELJEV V DRŽAVAH ČLANICAH**

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmacevtska oblika</u>	<u>Pot uporabe zdravila</u>
AT - Avstrija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
AT - Avstrija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
AT - Avstrija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
BE - Belgija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 mcg/ 5 mcg, aërosol, suspensie	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
BE - Belgija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 mcg/ 5 mcg, aërosol, suspensie	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

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BE - Belgija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 mcg/ 10 mcg, aërosol, suspensie	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
BG - Bolgarija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
BG - Bolgarija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
BG - Bolgarija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
CY - Ciper	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
CY - Ciper	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

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CY - Ciper	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
CZ - Češka	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
CZ - Češka	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
CZ - Češka	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
DK - Danska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
DK - Danska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmaceutska oblika</u>	<u>Pot uporabe zdravila</u>
DK - Danska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
FI - Finska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
FI - Finska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
FI - Finska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
FR - Francija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
FR - Francija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmaceutska oblika</u>	<u>Pot uporabe zdravila</u>
FR - Francija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
DE - Nemčija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
DE - Nemčija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
DE - Nemčija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IS - Islandija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IS - Islandija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmaceutska oblika</u>	<u>Pot uporabe zdravila</u>
IS - Islandija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IE - Irska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IE - Irska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IE - Irska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IT - Italija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
IT - Italija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmaceutska oblika</u>	<u>Pot uporabe zdravila</u>
IT - Italija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
LU - Luksemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
LU - Luksemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
LU - Luksemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
NL - Nizozemska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 microgram /5 microgram /dosis aërosol, suspensie	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
NL - Nizozemska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 microgram /5 microgram /dosis aërosol, suspensie	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

<u>Država članica EU/EGP</u>	<u>Predlagatelj</u>	<u>Izmišljeno ime</u>	<u>Jakost</u>	<u>Farmaceutska oblika</u>	<u>Pot uporabe zdravila</u>
NL - Nizozemska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 microgram /10 microgram /dosis aërosol, suspensie	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
NO - Norveška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
NO - Norveška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
NO - Norveška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
PL - Poljska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
PL – Poljska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

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PL – Poljska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
PT – Portugalska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
PT – Portugalska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
PT – Portugalska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
RO – Romunija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 micrograme/5 micrograme suspensie de inhalat presurizată	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

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RO – Romunija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 micrograme /5 micrograme suspensie de inhalat presurizată	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
RO – Romunija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 micrograme /10 micrograme suspensie de inhalat presurizată”	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
SK - Slovaška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 50/5 µg	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
SK - Slovaška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 125/5µg	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
SK - Slovaška	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 250/10 µg	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
SE - Švedska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje

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SE - Švedska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
SE - Švedska	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
UK - Velika Britanija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	50mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
UK - Velika Britanija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	125mcg/5mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje
UK - Velika Britanija	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	250mcg/10mcg	Inhalacijska suspenzija pod tlakom	Za inhaliranje