

ANHANG I

**VERZEICHNIS DER BEZEICHNUNGEN, DARREICHUNGSFORM, STÄRKE DES
ARZNEIMITTELS, ART DER ANWENDUNG, DER ANTRAGSTELLER IN DEN
MITGLIEDSTAATEN**

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
AT - Österreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
AT - Österreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
AT - Österreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
BE - Belgien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 mcg/ 5 mcg, aërosol, suspensie	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
BE - Belgien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 mcg/ 5 mcg, aërosol, suspensie	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
BE - Belgien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 mcg/ 10 mcg, aërosol, suspensie	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
BG - Bulgarien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
BG - Bulgarien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
BG - Bulgarien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
CY - Zypern	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
CY - Zypern	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
CY - Zypern	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
CZ - Tschechische Republik	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
CZ - Tschechische Republik	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
CZ - Tschechische Republik	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
DK - Dänemark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
DK - Dänemark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
DK - Dänemark	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
FI - Finnland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
FI - Finnland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
FI - Finnland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
FR - Frankreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
FR - Frankreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
FR - Frankreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
DE - Deutschland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
DE - Deutschland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
DE - Deutschland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
IS - Island	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
IS - Island	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
IS - Island	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
IE - Irland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
IE - Irland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
IE - Irland	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
IT - Italien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
IT - Italien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
IT - Italien	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiformo®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
LU - Luxemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
LU - Luxemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
LU - Luxemburg	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
NL - Niederlande	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 50 microgram /5 microgram /dosis aérosol, suspensie	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
NL - Niederlande	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 125 microgram /5 microgram /dosis aérosol, suspensie	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
NL - Niederlande	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® Flutiform 250 microgram /10 microgram /dosis aérosol, suspensie	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
NO - Norwegen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
NO - Norwegen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
NO - Norwegen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
PL - Polen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
PL - Polen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
PL - Polen	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
PT - Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
PT - Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
PT - Portugal	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
RO - Rumänien	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	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
RO - Rumänien	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	Druckgasinhalation, Suspension	Zur Inhalation
RO - Rumänien	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	Druckgasinhalation, Suspension	Zur Inhalation
SK - Slowakei	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 50/5µg	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
SK - Slowakei	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 125/5µg	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
SK - Slowakei	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform® 250/10µg	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
SE - Schweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation

<u>Mitgliedstaat EU/EWR</u>	<u>Antragsteller</u>	<u>Phantasiebezeichnung</u>	<u>Stärke</u>	<u>Darreichungsform</u>	<u>Art der Anwendung</u>
SE - Schweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
SE - Schweden	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flutiform®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation
UK - Vereinigtes Königreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	50mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
UK - Vereinigtes Königreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	125mcg/5mcg	Druckgasinhalation, Suspension	Zur Inhalation
UK - Vereinigtes Königreich	Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom	Flofera®	250mcg/10mcg	Druckgasinhalation, Suspension	Zur Inhalation