

ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL
PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS
IN THE MEMBER STATES**

<u>Member State</u> <u>EU/EEA</u>	<u>Marketing Authorisation</u> <u>Holder</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of administration</u>	<u>Content (concentration)</u>
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 10mg – Kapseln	10 mg	capsule, hard	Oral use	
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 20mg – Kapseln	20 mg	capsule, hard	Oral use	
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 40 mg - Trockenstechampulle mit Lösungsmittel	40 mg	Powder for solution for injection	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec 40mg Forte, harde maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec 40 mg, poeder voor oplossing voor intraveneuze infusie	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 10mg, 10 mg, maagsapresistente tabletten	10 mg	Gastroresistant tablets	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 20mg, 20 mg, maagsapresistente tabletten	20 mg	Gastroresistant tablets	Oral use	

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Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 40mg, 40 mg, maagsapresistente tabletten	40 mg	Gastroresistant tablets	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussel Belgium	Omeprazole AstraZeneca 20mg, harde maagsapresistente capsules	20 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussel Belgium	Omeprazole AstraZeneca 40mg Forte, harde maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Omeprazole AstraZeneca 40mg, poeder voor oplossing voor intraveneuze infusie	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 10mg, maagsapresistente capsules	10 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 20mg, maagsapresistente capsules	20 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 40mg Forte, maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	

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Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric-Mups 40mg, 40 mg, maagsapersistenten tabletten	40 mg	Gastroresistant tablets	Oral use	
Cyprus	AstraZeneca AB, 151 85 Södertälje Sweden	Losec Mups	10mg	Gastro-resistant tablets	Oral use	
Cyprus	AstraZeneca AB, 151 85 Södertälje Sweden	Losec Mups	20mg	Gastro-resistant tablets	Oral use	
Czech Republic	AstraZeneca UK Ltd., Silk Road Business Park ,SK10 2NA Macclesfield, Cheshire, United Kingdom	LOSEC 20 mg	20 mg	Gastro-resistant capsule, hard	Oral use	
Czech Republic	AstraZeneca UK Ltd., Silk Road Business Park ,SK10 2NA Macclesfield, Cheshire, United Kingdom	LOSEC 40 mg	40 mg	Powder for solution for infusion	Intravenous use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	10 mg	Gastroresistant tablets	Oral use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	20 mg	Gastroresistant tablets	Oral use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg	Gastroresistant tablets	Oral use	

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Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg/ml	Powder and Solvens for solution for injection	Intravenous use	40 mg
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg/ml	Powder for solution for infusion	Intravenous use	40 mg
Estonia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS	20 mg	Gastroresistant tablets	Oral use	
Estonia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 MG	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 10 mg enterotabletti	10 mg	Gastroresistant tablet	Oral use	
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 20 mg enterotabletti	20 mg	Gastroresistant tablet	Oral use	
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 40 mg enterotabletti	40 mg	Gastroresistant tablet	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL® 20 mg microgranules gastrorésistants en gélule	20 mg	Capsules	Oral use	

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France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL® 10 mg microgranules gastrorésistants en gélule	10 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	ZOLTUM® 20 mg microgranules gastrorésistants en gélule	20 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	ZOLTUM® 10 mg microgranules gastrorésistants en gélule	10 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL 40 mg, lyophilisat pour perfusion (IV).	40 mg	Lyophilizat for perfusion	Intravenous use	40 mg
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra pro infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 10 mg	10 mg	Gastro-resistant tablets	Oral use	
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 20 mg	20 mg	Gastro-resistant tablets	Oral use	

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Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 40 mg	40 mg	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec [®] , Γαστροανθεκτικό καψάκιο σκληρό 10 mg/CAP	10 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec [®] , Γαστροανθεκτικό καψάκιο σκληρό 20 mg/CAP	20 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec [®] , Γαστροανθεκτικό καψάκιο σκληρό 40 mg/CAP	40 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS [®] , Γαστροανθεκτικό δισκίο 10 mg/TAB	10 mg	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS [®] , Γαστροανθεκτικό δισκίο 20 mg/TAB	20 m	Gastro-resistant tablets	Oral use	

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Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS [®] , Γαστροανθεκτικό δισκίο 40 mg/TAB	40 mg	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec [®] , Ενέσιμο λυόφιλο 40 mg/VIAL	40 mg	Powder and solvent for solution for injection	Intravenous use	40 mg
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec [®] , Ενέσιμο λυόφιλο για ενδοφλέβια έγχυση 40 mg/VIAL	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 10 mg kapszula	10 mg	Capsule, hard	Oral use	
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 20 mg kapszulaz	20 mg	Capsule, hard	Oral use	
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 40 mg por infúzióhoz	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	10 mg	Gastroresistant tablets	Oral use	

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Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	20 mg	Gastroresistant tablets	Oral use	
Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 10mg	10mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 20mg	20mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 40mg	40mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Losec 40mg Powder for Solution for Infusion	40mg	Powder for solution for infusion	Intravenous use	40 mg
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec IV 40mg Powder and Solvent for Solution for Injection	40mg	Powder and solvent for solution for injection	Intravenous use	40 mg

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Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	

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Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	

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Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Latvia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg pulveris infūziju šķīduma pagatavošanai	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec Forte Gelules 40mg	40 mg	Hard gastroresis-tant capsules	Oral use	
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec poudre pour perfusion 40 mg	40 mg	Powder for solution for intravenous infusion	Intravenous use	40 mg
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 10mg	10 mg	Gastroresistant tablets	Oral use	
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 20mg	20 mg	Gastroresistant tablets	Oral use	

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Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 40mg	40 mg	Gastroresistant tablets	Oral use	
Malta	AstraZeneca AB S-151 85 Södertälje Sweden	Losec MUPS Tablets 10mg	10mg	Gastro-resistant, film-coated tablet	Oral use	
Malta	AstraZeneca AB S-151 85 Södertälje Sweden	Losec MUPS Tablets 20mg	20mg	Gastro-resistant, film-coated tablet	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 10	10 mg	Gastroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 20	20 mg	Gastroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 40	40 mg	Gastroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec	40 mg	Powder and solvent for solution for injection	Intravenous use	40 mg
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec Infuus	40 mg	Powder for solution for intravenous infusion	Intravenous use	40 mg

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Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 10	10 mg	Gastroresistant tablets	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 20	20 mg	Gastroresistant tablets	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 40	40 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec [®] MUPS [®]	10 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec [®] MUPS [®]	20 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec [®]	40mg	Powder for solution for infusion	Intravenous use	40 mg
Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec 10	10mg	Capsules	Oral use	
Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	20mg	Capsules	Oral use	

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Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40mg	Powder for solution for infusion	Intravenous use	40 mg
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	20 mg	Gastroresistant capsules	Oral use	
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	40 mg	Powder and solvent for injectable solution	Intravenous use	40 mg
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS 10 mg coprimate filmate gastrorezistente	10 mg	Film-coated gastroresistant tablets	Oral use	
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS 20 mg coprimate filmate gastrorezistente	20mg	Film-coated gastroresistant tablets	Oral use	
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40mg liofilizat pentru solutie perfuzabila	40mg	Lyophilisate for solution for infusion	Intravenous use	40 mg

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Slovak Republic	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec [®]	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Spain	Laboratorio Tau, S.A. C/ Serrano Galvache, 56 Edificio Roble 28033 Madrid Spain	LOSEC infusión i.v.	40 mg	Powder for infusion	Intravenous use	40 mg
Spain	Laboratorio Tau, S.A. C/ Serrano Galvache, 56 Edificio Roble 28033 Madrid Spain	LOSEC cápsulas 20 mg	20 mg	Capsules, hard	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	10 mg	Gastro-resistant tablets	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	20 mg	Gastro-resistant tablets	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Gastro-resistant tablets	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Powder for solution for injection	Intravenous use	40 mg
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg

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United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 10mg	10mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 20mg	20mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 40mg	40mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 10mg	10mg	Hard gelatin capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 20mg	20mg	Hard gelatin capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 40mg	40mg	Hard gelatine capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Infusion 40mg	40mg	Powder for solution for infusion	Intravenous use	40 mg

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United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec IV Injection 40mg	40mg	Powder and solvent for solution for injection	Intravenous use	40 mg