

Annex I

List of the names, pharmaceutical form, strengths of the medicinal products, route of administration, marketing authorisation holders in the member states

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin 12 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	12 mg	Powder and solvent for solution for injection	Subcutaneous use
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin 5,3 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Austria	Pfizer Corporation Austria GmbH Floridsdorfer Hauptstraße 1 A-1210 Wien Austria	Genotropin MiniQuick 0,2 mg - Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	1,3 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	5,0 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	5,3 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm	12 mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,2 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,4 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,6 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	0,8 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,0 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,2 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,4 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	PFIZER S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,6 mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	Pfizer S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	1,8 mg	powder and solvent for solution for injection	Subcutaneous use
Belgium	Pfizer S.A. Boulevard de la Plaine, 17 1050 Brussels Belgium	Genotonorm MiniQuick	2,0 mg	powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	1,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	5 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin	12 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,0 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
Denmark	Pfizer ApS, Lautrupvang 8, DK-2750 Ballerup, Denmark	Genotropin Miniquick	2,0 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Genotropin	5 mg	Powder and solvent for solution for injection	Subcutaneous use
Finland	Pfizer Oy, Tietokuja 4, 00330 Helsinki, Finland	Genotropin	12 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 5mg, poudre et solvant pour solution injectable	5 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 5,3 mg, poudre et solvant pour solution injectable	5,3 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM 12mg, poudre et solvant pour solution injectable	12 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,2 mg, poudre et solvant pour solution injectable	0,2 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,4 mg, poudre et solvant pour solution injectable	0,4 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,6 mg, poudre et solvant pour solution injectable	0,6 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 0,8 mg, poudre et solvant pour solution injectable	0,8 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1 mg, poudre et solvant pour solution injectable	1 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,2 mg, poudre et solvant pour solution injectable	1,2 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,4 mg, poudre et solvant pour solution injectable	1,4 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,6 mg, poudre et solvant pour solution injectable	1,6 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 1,8 mg, poudre et solvant pour solution injectable	1,8 mg	Powder and solvent for solution for injection	Subcutaneous use
France	Pfizer Holding France, 23-25 avenue du Docteur Lannelongue, 75014 Paris France	GENOTONORM MINIQUICK 2 mg, poudre et solvant pour solution injectable	2 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 5 mg/ml	5.0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 5,3 mg/ml	5.3 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	Genotropin 12 mg/ml	12.0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,2 mg	0.2 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,4 mg	0.4 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,6 mg	0.6 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 0,8 mg	0.8 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,0 mg	1.0 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,2 mg	1.2 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1.4 mg	1.4 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 1,6 mg	1.6 mg	Powder and solvent for solution for injection	Subcutaneous use
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin	GENOTROPIN MiniQuick 1,8 mg	1.8 mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Pharmacia GmbH Linkstr. 10 D-10785 Berlin Germany	GENOTROPIN MiniQuick 2,0 mg	2.0 mg	Powder and solvent for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1,4mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	2mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	5mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN (WITH PRESERVATIVE)	5,3 mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN (WITH PRESERVATIVE)	12mg	Powder and Solution for solution for injection	Subcutaneous use
Greece	PFIZER HELLAS A.E. MESSOGHION AVE. 243 15451 NEO PSYCHIKO Greece	GENOTROPIN	1,3mg	Powder and Solution for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 5.3MG	5.3 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 12MG	12 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.2 MG	0.2 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.4 MG	0.4 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.6 MG	0.6 mg	Powder and solvent for Solution for injection	Subcutaneous Use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.8 MG	0.8 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1 MG	1 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.2 MG	1.2 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.4 MG	1.4 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.6 MG	1.6 mg	Powder and solvent for Solution for injection	Subcutaneous Use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.8 MG	1.8 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Ireland	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 2 MG	2 mg	Powder and solvent for Solution for injection	Subcutaneous Use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin	5,3 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin	12 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,2 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,4 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,6 mg	powder and solvent for solution for injection	subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	0,8 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,2 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,4 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,6 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	1,8 mg	powder and solvent for solution for injection	subcutaneous use
Italy	Pfizer Italia S.r.l. Via Valbondione 113 00188 Rome Italy	Genotropin Miniquick	2 mg	powder and solvent for solution for injection	subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	1.3 mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	5mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	5.3mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm	12mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,2mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,4mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,6mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	0,8mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,2mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,4mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,6mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	1,8mg	powder and solvent for solution for injection	Subcutaneous use
Luxembourg	Pfizer SA 17, Boulevard de la Plaine B-1050 Bruxelles Belgium	Genotonorm Miniquick	2mg	powder and solvent for solution for injection	Subcutaneous use
Netherlands	Pfizer BV Postbus 37 2900AA Capelle aan den Ijssel The Netherlands	Genotropin 5 mg, poeder en oplosmiddel voor oplossing voor injectie	5mg	powder and solvent for solution for injection	Subcutaneous use
Netherlands	Pfizer BV Postbus 37 2900AA Capelle aan den Ijssel The Netherlands	Genotropin 12mg, poeder en oplosmiddel voor oplossing voor injectie	12mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 1,3 mg	1.3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 12 mg	12 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin 5,3 mg	5.3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Mixer	5.3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	2 mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0.2 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0.4 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0.6 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	0.8 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1.2 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1.4 mg	powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1.6 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Miniquick	1.8 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin Mixer	1.3 mg	powder and solvent for solution for injection	Subcutaneous use
Portugal	Laboratórios Pfizer, Lda. Lagoas Park, Edifício 10 2740-271 Porto Salvo Portugal	Genotropin	5 mg	powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM KABIPEN 12 mg polvo y disolvente para solución inyectable	12mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM KABIPEN 5,3 mg polvo y disolvente para solución inyectable	5,3mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,2 mg polvo y disolvente para solución inyectable	0,2mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,4 mg polvo y disolvente para solución inyectable	0,4mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,6 mg polvo y disolvente para solución inyectable	0,6mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 0,8 mg polvo y disolvente para solución inyectable	0,8mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1 mg polvo y disolvente para solución inyectable	1mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,2 mg polvo y disolvente para solución inyectable	1,2mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,4 mg polvo y disolvente para solución inyectable	1,4mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,6 mg polvo y disolvente para solución inyectable	1,6mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 1,8 mg polvo y disolvente para solución inyectable	1,8mg	Powder and solvent for solution for injection	Subcutaneous use
Spain	PFIZER, S.A. Avda. de Europa, 20 B. Parque Empresarial La Moraleja Alcobendas 28108 MADRID Spain	GENOTONORM MINIQUICK 2 mg polvo y disolvente para solución inyectable	2mg	Powder and solvent for solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin	5.3 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin	12 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin	5 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,2 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,4 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,6 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	0,8 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1 mg	Powder and solution for injection	Subcutaneous use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,2 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,4 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,6 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	1,8 mg	Powder and solution for injection	Subcutaneous use
Sweden	Pfizer AB , 191 90 Sollentuna, Sverige Sweden	Genotropin Mini Quick	2 mg	Powder and solution for injection	Subcutaneous use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ	GENOTROPIN 5.3 MG	5.3mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN 12MG	12mg	Powder and solvent for solution for injection	Subcutaneous Use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.2MG	0.2mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.4MG	0.4mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.6MG	0.6mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 0.8MG	0.8mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1MG	1mg	Powder and solvent for solution for injection	Subcutaneous Use

Member State	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.2MG	1.2mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.4MG	1.4mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.6MG	1.6mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 1.8MG	1.8mg	Powder and solvent for solution for injection	Subcutaneous Use
United Kingdom	Pharmacia Laboratories Limited Ramsgate Road Sandwich Kent CT13 9NJ United Kingdom	GENOTROPIN MINIQUICK 2MG	2mg	Powder and solvent for solution for injection	Subcutaneous Use

Annex II

**Scientific conclusions and grounds for refusal presented by the European
Medicines Agency**

Scientific conclusions

Overall summary of the scientific evaluation of Genotropin and associated names (see annex I)

Genotropin and associated names is a recombinant human growth hormone that has received marketing authorisation in the European Union under the different names listed in annex I.

On 30 July 2008, the MAH submitted a type II variation via the mutual recognition procedure for Genotropin and associated names (DK/H/0012/001,004-6,008-024/II/118), to request an extension of the indications.

As the Reference and Concerned member States were not able to reach an agreement in respect of the variation, on 28 October 2009, the Netherlands triggered a referral under Article 6(12) of Commission Regulation EC No 1084/2003. The CHMP was requested to give its opinion on whether the marketing authorisations should be varied to include the indication:

Growth disturbance in children with severe forms of juvenile idiopathic arthritis (JIA), requiring long term glucocorticoid treatment, for improvement of growth and body composition. The diagnosis of growth disturbance should be confirmed by a current height SDS < -2 or a growth velocity SDS ≤ -1 , measured over a period of at least 12 months.

The procedure was initiated on 17 November 2009.

Juvenile idiopathic arthritis (JIA) is an inflammatory disorder, causing swelling, synovitis, pain, stiffness, and/or tenderness of one or multiple joints, and may also cause inflammation of other organs. The etiology is largely unknown, but it is likely that autoimmune factors play a role. The diagnosis is made by exclusion of other known, specific conditions causing arthritis and requires objective evidence of arthritis of at least 6 weeks duration in children younger than 16 at time of onset.

The most severe forms of JIA often require aggressive therapy with disease modifying antirheumatic drugs (DMARDs), including biologicals, methotrexate, cyclosporine and glucocorticoids to control inflammation, arthritis and other clinical manifestations. Due to the chronic nature of the disease with recurrent flares, long term therapy with glucocorticoids is often necessary after the initial diagnosis. In about 20% of the optimal treated patients, glucocorticoid treatment is necessary. Although glucocorticoid therapy leads to significant improvement of signs and symptoms, it is invariably associated with substantial growth impairment and alterations in body composition in the majority of treated children.

The application submitted by the MAH contained 4 company sponsored studies, including 2 pivotal trials, and 2 investigator initiative studies:

Pivotal study CTC-3 was a phase 3, open-label, randomised, controlled, 36-months prospective, single center study that evaluated early treatment with Genotropin versus untreated controls in the prevention of growth retardation of children with severe JIA requiring long-term corticosteroid therapy. The study included a total of 30 patients randomized to receive no treatment (controls) or Genotropin at the dose of 0.066 mg/mg/day.

Pivotal study CTC-4 was a phase 3, non-randomised, non-controlled, 36-month, open-label study that evaluated genotropin in prepubertal or pubertal children with short stature secondary to long-term glucocorticoid therapy for treatment of JIA or nephritic syndrome. The study was conducted in 2 centers in France and included a total of 30 subjects who received Genotropin at the dose of 0.066 mg/kg/day.

Supportive study CTC-1 was a non-randomised, non-controlled, open-label, single center pilot study that evaluated Genotropin in prepubertal children with short stature secondary to long-term glucocorticoid therapy for treatment of JIA. A total of 15 patients received Genotropin for 12 months at the dose of 0.066 mg/kg/day followed by 12 months without Genotropin treatment.

Supportive study CTC-2 was a non-randomised, non-controlled, open-label, single center study that evaluated Genotropin in children with JIA and short stature secondary to glucocorticoid

therapy. The study population included 13 children who had previously completed CTC-1. In CTC-2, all subjects received Genotropin 0.066 mg/kg/day for 36 months.

Two investigator-initiated studies (Bechtold and Grote) were also included in the application. These were randomized, controlled studies that compared Genotropin versus an untreated control group in JIA children with severe growth retardation. The study designs and efficacy endpoints were similar as those of the pivotal/supportive studies, except that smaller doses were used (0.029 - 0.047 mg/kg/day in Bechtold and 0.045 mg/kg/day in Grote).

Efficacy

Despite the recent introduction of biological therapies as an alternative for JIA patients, the medical need for treatment in the proposed population still exists. Data from the German national JIA registry indicates that, in 2007, around 20% of the 1941 subjects under the age of 18 required ongoing systemic glucocorticoid treatment. Biological therapies are not effective in all patients therefore, while in absolute figures the population under discussion may now be smaller than in the past, there is still an unmet medical need.

However, even if it is understood that the population eligible for treatment is limited, the efficacy database in absolute numbers is small. A total of only 68 subjects treated with Genotropin were included in the 6 studies submitted with the application. Only 4 of the 6 studies were conducted by the MAH (the remaining were investigator initiated published studies), and only 1 of these 4 included a control group. While it is recognized that data from different sources seems to be consistent and to indicate a possible positive effect of growth hormone on growth velocity in this indication, the existing data is too limited to draw a conclusion on the efficacy.

Dose selection

The proposed dose, 0.047 mg/kg/day, was only used in one of the investigator published studies. This dose was not used in the pivotal trials or in the supportive trials. Therefore it is considered by the Committee that efficacy in the proposed dose for the proposed indication is not adequately demonstrated.

Final height

In all the studies presented, growth velocity increased with Genotropin treatment above control and/or baseline values. However very limited data is available on final height for the pivotal trials, so the benefit of the treatment in the proposed indication was not adequately demonstrated. The majority of data on final height comes from 13 Genotropin subjects in the Bechtold study, where many of the confounding factors were not adequately addressed, therefore it is not possible to draw conclusions from these data.

Improvement in body composition and Bone Mineral Density (BMD)

In the studies conducted by the MAH, no clear and significant effect of Genotropin therapy was demonstrated on improvement of body composition or BMD.

Clinical benefits

Although the benefits of increased height in quality of life are accepted in some of the other indications (growth hormone deficiency), they have not been clearly demonstrated in this indication. The pivotal trials supporting the application did not include information on quality of life, in addition to the lack of information on final height.

The CHMP Scientific Advisory Group (SAG) on Diabetes/Endocrinology was consulted on these issues and took the view that the data were suggestive of a short-term benefit of therapy, however there is little information on final height so considerable extrapolation would be required to conclude on the efficacy in this indication. The SAG also expressed the opinion that, while this treatment could potentially represent a significant benefit for some patients, the data submitted did not demonstrate the occurrence of clinical benefits such as protection against bone loss, improvement in lean body mass, muscle strength or well being in the subjects of the studies.

Safety

Overall, in the studies presented, the safety profile was comparable to that of other Genotropin indications and consistent with its pharmacological class.

However the potential for development of malignancies may be higher in this patient group than in other indications, in view of the concomitant immunosuppression required in JIA. It should be noted that baseline IGF-1 is usually low in JIA patients and may be further reduced by steroids. The long term effects of the combination between growth hormone and corticosteroids are not known, and were not investigated in the studies presented.

The acute diabetogenic effect of growth hormone is well-known. The Bechtold study, the only one where the proposed dose (0.047 mg/kg/day) was used, did not reveal any glucose abnormalities. However, diabetes remains as a concern in these patients as the long term effects of the combination between growth hormone and corticosteroids are not known and were not investigated.

The CHMP SAG on Diabetes/Endocrinology was consulted and expressed concerns regarding the long-term safety of the product. Whilst the acute safety was considered to raise little concern, the uncertainty regarding long-term safety was highlighted by the SAG experts.

Benefit-Risk

Regarding safety, concerns exist on the potential long term risks associated with growth hormone treatment (such as tumour promotion or diabetes), which may be aggravated in this indication by the prolonged concomitant administration of corticosteroids. The long term safety of the combination between glucocorticoids and growth hormone was not addressed in the trials conducted.

In the pivotal trials conducted by the MAH, a dose higher than the dose proposed was used and, as very limited final height data is available, the clinical relevance of the effect was not demonstrated.

Data from the MAH sponsored trials, as well as the Bechtold study, failed to prove a clinically relevant effect on final height, BMD and body composition. In addition, information on quality of life was not collected in any of the sponsored trials. The absence of such information makes the scarce data available of limited value. The impact of growth hormone treatment on these clinically relevant endpoints in this indication is unclear.

Based on the above, the CHMP concluded that the application does not satisfy the criteria for authorisation in respect of safety and efficacy.

Grounds for refusal

Whereas

- The Committee considered the referral made under article 6(12) of Commission Regulation (EC) No 1084/2003;
- The Committee considered that there are potential long term risks associated with growth hormone treatment (such as tumour promotion or diabetes), which may be aggravated in this indication by the prolonged concomitant administration of corticosteroids;
- The Committee considered that the Marketing Authorisation Holders did not present data demonstrating the efficacy of Genotropin in the proposed indication and for the proposed posology.
- The Committee considered that the benefit risk balance of the product in the proposed indication is not positive.
- The Committee, as a consequence, concluded that the variation application does not satisfy the criteria for authorisation in respect of safety and efficacy.

the CHMP has recommended the refusal of the variation of the Marketing Authorisations.