

SUMMARY OF PRODUCT

STRUCTURE

The data presented in this section refer to (recombinant) human interferon beta-1a (huIFN- β) in general. The information provided was obtained from the scientific literature and the National Center for Biological Information (NCBI) internet resource.

The IFN beta-1a Drug Substance was characterised using a range of state-of-the-art orthogonal methodologies to elucidate the primary, secondary, and higher order structure, post-translational modifications and associated micro-heterogeneity, purity, and biological activity.

CinnaGen's Interferon beta 1a is a glycoprotein produced by recombinant DNA technology in Chinese Hamster Ovary cells (CHO cell line 17A1(10)16). The glycoprotein has a chain length of 166 amino acids and relative molecular mass of approximately 22,500 Daltons.

Amino Acid Sequence of Interferon beta -1

The amino acid sequence, predicted from the cDNA, is shown in the figure below. The *N*-glycosylation site at Asn80 (red) and the intramolecular disulfide bond Cys31–Cys141 (green) are indicated:

Figure 1: Amino Acid Sequence of Interferon beta 1a

5	10	15	20
MetSerTyrAsnLeu	LeuGlyPheLeuGln	ArgSerSerAsnPhe	GlnCysGlnLysLeu
25	30	35	40
LeuTrpGlnLeuAsn	GlyArgLeuGluTyr	CysLeuLysAspArg	MetAsnPheAspIle
45	50	55	60
ProGluGluIleLys	GlnLeuGlnGlnPhe	GlnLysGluAspAla	AlaLeuThrIleTyr
65	70	75	80
GluMetLeuGlnAsn	IlePheAlaIlePhe	ArgGlnAspSerSer	SerThrGlyTrpAsn
85	90	95	100
GluThrIleValGlu	AsnLeuLeuAlaAsn	ValTyrHisGlnIle	AsnHisLeuLysThr
105	110	115	120
ValLeuGluGluLys	LeuGluLysGluAsp	PheThrArgGlyLys	LeuMetSerSerLeu
125	130	135	140
HisLeuLysArgTyr	TyrGlyArgIleLeu	HisTyrLeuLysAla	LysGluTyrSerHis
145	150	155	160
CysAlaTrpThrIle	ValArgValGluIle	LeuArgAsnPheTyr	PheIleAsnArgLeu
165	170	175	180
ThrGlyTyrLeuArg	Asn		

Nomenclature information of Interferon beta-1a.

Recommended International Nonproprietary Name (INN)	Interferon beta-1a
Anatomical Therapeutic Chemical (ATC) code	L03 AB07
Chemical Name	Recombinant Human Interferon beta-1a
Other name	r-HuIFN-β, Recombinant Human Fibroblast Interferon, Recombinant Interferon, IFN beta-1a
Laboratory code	28 and 25
Chemical Abstracts Service (CAS) registry number	145258-61-3
Molecular Formula	C908H1408O252S7
Molecular weight	~ 23 KDa
United States Adopted Name (USAN)	Interferon beta-1a
Japanese Accepted Name (JAN)	Interferon beta-1a (Genetical Recombinaion)
British Approved Name (BAN)	Interferon beta-1a

Name of the medicinal product

Interferon Beta-1a 44 mcg/0.5 ml solution for injection in prefilled syringe

Reference Product

Rebif from Merck Serono

Quantitative and Qualitative composition

ReciGen

Each pre-filled syringe contains 44 micrograms (12 million International Units) of interferon beta-1a. ReciGen® is produced by recombinant DNA technology using genetically engineered Chinese Hamster Ovary cells into which the human interferon beta gene has been introduced. Each syringe of ReciGen consist of HSA (Human Serum Albumin), D-Mannitol, Acetate Buffer and Water for Injection.

ReciGen HSA free

Each prefilled syringe contains 44 micrograms (12 million International Units) of interferon beta-1a.

ReciGen® is produced by recombinant DNA technology using genetically engineered Chinese Hamster Ovary cells into which the human interferon beta gene has been introduced. Each syringe of ReciGen HSA free consist of Poloxamer 188, Mannitol,L-Methionine,Benzyl Alcohol,Acetate Buffer and Water for Injection.

Therapeutic indications

Relapsing forms of multiple sclerosis

Pharmacological properties

Pharmacotherapeutic Group: Interferons,ATC code: L03 AB07

Route of Administration

SC