

## **SUMMARY OF PRODUCT**

### **STRUCTURE**

The data presented in this section refer to (recombinant) human interferon beta-1a (huIFN- $\beta$ ) 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:

**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.**

<b>Recommended International Nonproprietary Name (INN)</b>	Interferon beta-1a
<b>Anatomical Therapeutic Chemical (ATC) code</b>	L03 AB07
<b>Chemical Name</b>	Recombinant Human Interferon beta-1a
<b>Chemical Abstracts Service (CAS) registry number</b>	145258-61-3
<b>Molecular Formula</b>	C908H1408O252S7
<b>Molecular weight</b>	~ 23 KDa

**Name of the medicinal product**

Interferon Beta-1a 30 mcg/vial , lyophilized powder for injection, solvent for reconstitution in pre-filled syringe

Interferon Beta-1a 30 mcg/ 0.5 ml solution for injection in prefilled syringe

**Reference Product**

Avonex from Biogen

**Quantitative and Qualitative composition****Lyophilysed CinnoVex**

Each vial contains 30 micrograms (6 million International Units) of interferon beta-1a, one pre-filled syringe contains 1.0 ml solvent (water for injection) for reconstitution. CinnoVex® is produced by recombinant DNA technology using genetically engineered Chinese Hamster Ovary cells into which the human interferon beta gene has been introduced. Each vial of CinnoVex consists of Human Serum Albumin, Dibasic sodium phosphate, Monobasic sodium phosphate, Sodium chloride and Water for injection.

**Liquid CinnoVex**

Each syringe contains 30 micrograms (6 million International Units) of interferon beta-1a. CinnoVex® is produced by recombinant DNA technology using genetically engineered Chinese Hamster Ovary cells into which the human interferon beta gene has been introduced. The amino acid sequence of CinnoVex® is identical to that of natural human interferon beta. Each syringe of CinnoVex consist of L-Arginine, Polysorbate 20,Sodium Acetate Trihydrate,Glacial Acetic Acid and Water for injection.

**Therapeutic indications**

Relapsing forms of multiple sclerosis

**Pharmacological properties**

Pharmacotherapeutic Group: Interferons

ATC code: L03 AB07

**Route of Administration**

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