



DEVELOPING THE FUTURE OF HEALTH



MAKING A
DIFFERENCE
IN THE EVERYDAY
LIVES OF
PATIENTS



AMEGAbiotech
A MEGALABS COMPANY

INTEGRATED
VALUE CHAIN
TO GUARANTEE
THE HIGHEST
QUALITY



AMEGA Biotech develops, produces and commercializes biopharmaceutical products for human health, from cell engineering to Active Pharmaceutical Ingredient production and Finished Dosage Forms manufacturing.

AMEGA Biotech uses a technology platform with state-of-the-art development facilities and equipment and specialized human resources. The power of a robust development platform drives AMEGA Biotech to solid bioprocesses, high portfolio and pipeline potential, full characterization and testing of recombinant proteins.

PROCESS

- Development, production, purification, characterization and testing of a broad range of recombinant products.
- Generation of Master Cell Bank and Working Cell Bank.

PRODUCTION

- High-end internationally-audited manufacturing plants.

FILL- FINISHING

- Established network of partners with GMP approved facilities allowing access to world markets.
- Guaranteed fill-finishing quality.

PRE-CLINICAL/ CLINICAL PLATFORM

- Experienced clinical team: oversees study protocols and information confirming quality, safety and efficacy of our products.

PROMOTION AND DISTRIBUTION

- Access to world markets through strategic alliances with leading local partners.
- Careful selection of potential distributors to create long standing partnerships.
- Marketing support.





FROM
API
TO
FDF



AMEGA BIOTECH SITES

Our production processes are carried out at the sites located in the provinces of Buenos Aires and Santa Fe (Argentina), supported by strong development, pre-clinical and Quality Control platforms.

2 PROCESS DEVELOPMENT SITES

■ [1100 M2]

2 PRODUCTION SITES

■ [+ 10000 M2]

PRE-CLINICAL AND CLINICAL STUDIES SITE

■ [520 M2]

AMEGA Biotech has a wide range of first and second generation biosimilars. Current portfolio is made up of 13 Active Pharmaceutical Ingredients and a broad range of Finished Dosage Forms commercialized in over 20 countries.

ETANERCEPT

INTERFERON ALFA-2A

INTERFERON ALFA-2B

PEG-INTERFERON ALFA-2B

INTERFERON BETA-1A

INTERFERON BETA-1B

ERYTHROPOIETIN

FILGRASTIM

PEG-FILGRASTIM

FSH

SOMATROPIN

INTERLEUKIN-2

MOLGRAMOSTIM

At AMEGA Biotech we all know that our work is making a difference in the lives of thousands of patients with serious diseases. We are committed to their health, their integration into society and the continuous improvement of their quality of life.



PORTFOLIO OF FINISHED PRODUCTS



Enerceptan[®]

Etanercept 25 mg | 50 mg

FOR SUBCUTANEOUS USE
Prefilled syringe

- In rheumatoid arthritis (RA)
- Substantial improvement in signs and symptoms
- Effective in monotherapy and combination therapy

50 mg AUTOINJECTOR



Peg-Neutropine[®]

Pegfilgrastim 6 mg

FOR SUBCUTANEOUS USE
Prefilled syringe 6 mg

- In patients receiving chemotherapy:
- Reduced febrile neutropenia
- Reduced severe neutropenia
- Reduced the need for hospitalization
- Reduced the need for anti-infectives

Folitime[®]

Recombinant Human Follitropin Alpha

FOR SUBCUTANEOUS USE

- 75 IU | Lyophilized Powder for injectable solution
- 300 IU | Injectable solution in prefilled cartridges
- 450 IU | Injectable solution in prefilled cartridges
- 900 IU | Injectable solution in prefilled cartridges
- High pregnancy rates in in-vitro fertilization treatments
- Optimized production of oocytes
- Administration of lower rFSH doses in comparison with uFSH



Neutropine[®]

Filgrastim 30 MIU

FOR INTRAVENOUS OR SUBCUTANEOUS USE
Prefilled syringe

- After chemotherapy
- Reduced neutropenia
- Reduced infections

Somactive[®]

Somatropin 4 IU

FOR SUBCUTANEOUS USE
Powder and solvent for solution for injection

- For the treatment of pediatric patients who have growth failure due to an inadequate secretion
- For the treatment of growth failure associated with Turner syndrome



Hemastim P[®]

Erythropoietin 2000 IU | 4000 IU

FOR INTRAVENOUS OR SUBCUTANEOUS USE
Ampoule

- Increases Hemoglobin Levels
- Reduces Transfusions
- Improve Quality of Life in anemic patients

Somactive LF[®]

Somatropin 5 mg | 10 mg | 15 mg | 30 mg

FOR SUBCUTANEOUS USE
Injectable solution



Hemastim P[®]

Erythropoietin 2000 IU | 4000 IU

FOR INTRAVENOUS OR SUBCUTANEOUS USE
Vial of lyophilized powder with supplied diluent.

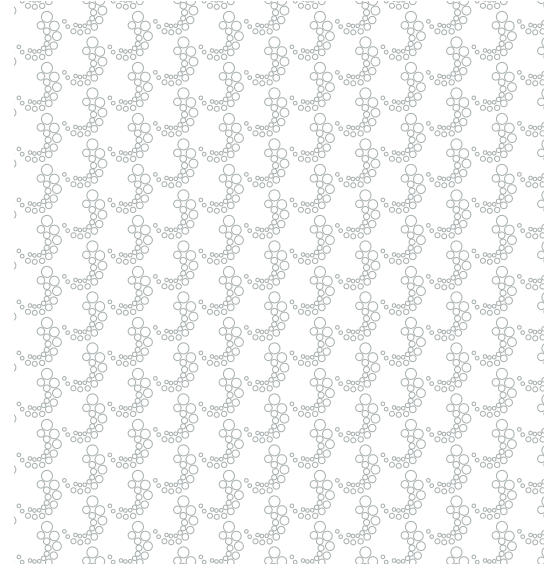
LYOPHILIZED

Interferon Beta 1-a 30 mcg

FOR INTRAMUSCULAR USE
Vial of lyophilized powder and prefilled syringe with supplied diluent

- In multiple sclerosis
- A single weekly dose
- Reduced disability progression
- Improved quality of life





GEMABIOTECH was born in 1998 and dedicated to research in the field of molecular biology. Founded by national capitals, it entered the pharmaceutical industry in 2005 to produce and commercialize active pharmaceutical ingredients of biotechnological origin.

GEMABIOTECH and Zelltek, another Argentine company pioneering the production of recombinant proteins, joined under the name of AMEGA Biotech to export its technology and products to the world.

By the end of 2014 GEMABIOTECH launched its first own biotechnology products in Argentina aiming at increasing patients' access to these high-tech medicines.

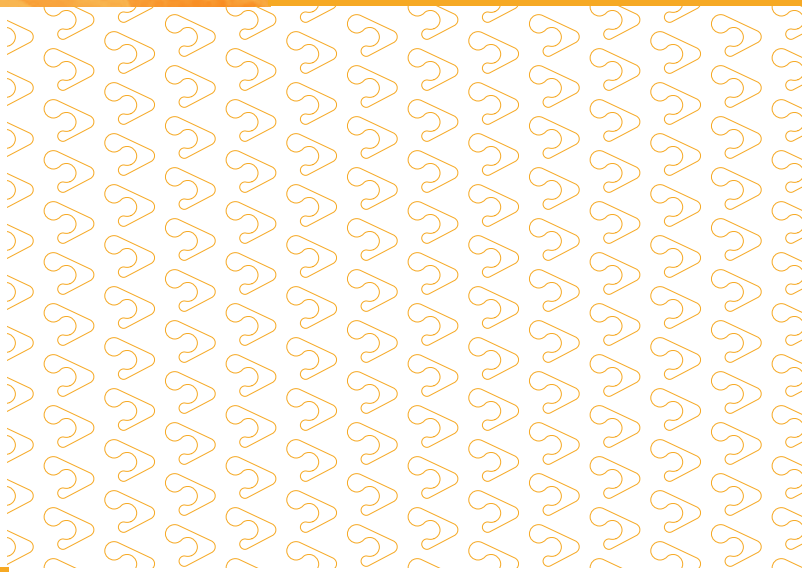
HIGH
TECHNOLOGY
MEDICINES





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GEMA | ZELLTEK
MEMBERS OF AMEGA BIOTECH


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