

3. About plasma & plasma protein therapies



Some 300,000 European patients rely on plasma protein therapies every day to treat a range of critical medical conditions.

These include rare, often genetic, diseases and chronic conditions, or life-threatening medical situations resulting from accidents and trauma.

For these patients, plasma-derived medicines are a lifeline, helping the body replace missing or deficient proteins. Without stable access to these treatments, many will not survive or have will a severely reduced quality of life.

Plasma - key facts

Life-saving treatment for many critical conditions and rare diseases.


Plasma-derived medicines help patients living with a range of rare diseases that can only be treated by these therapies. They are also used in everyday medicine, emergency and critical care situations and in preventive medicine.

Over the past five decades, plasma-derived medicines have improved lives, and given a better quality of life to millions of people. The wide use of plasma-based immunoglobulin therapies, has increased survival rates of patients with common variable immune deficiency (CVID) without disease-related complications, from 30% in 1979 to almost normal life expectancy today.

Clotting factor medicines derived from plasma have significantly extended the life expectancy of patients with severe haemophilia A, from 19 years before 1955 to 71 years in 2001. These therapies consistently achieve significant clinical results against primary endpoints – for example, an 80% reduction in bleeds for haemophilia patients and over 65% reduction in infections for patients with immune deficiencies.⁹

PER PATIENT PER YEAR:

MORE THAN
1200:  Plasma donations to treat ONE PATIENT for HAEMOPHILIA.

MORE THAN
900:  Plasma donations to treat ONE ALPHA-1 PATIENT.

MORE THAN
130:  Plasma donations to treat ONE PATIENT with a PRIMARY IMMUNE DEFICIENCY.

HOW PLASMA IS USED IN EVERYDAY MEDICINE



BURNS
(Albumin)



MAJOR SURGERY
(Albumin)



ORGAN TRANSPLANTS
(Anti-CMV IG)



LIVER CONDITIONS
(Albumin)



SHOCK
(Albumin)



RH INCOMPATIBILITY
Hemolytic disease of the new born



PAEDIATRIC HIV
Immune globulins



ANIMAL BITES
(Anti-Tetanus IG)



TRAUMA
(Albumin)



MAJOR CARDIAC SURGERIES
(Albumin)

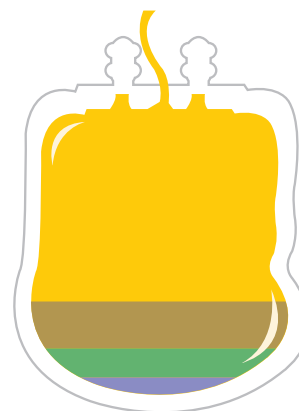


HEPATITIS
(Anti-HBV IG)



AUTO-IMMUNE DISEASES
(Immune globulins)

PLASMA PROTEINS AND THE DISEASES THEY TREAT



■ Albumin (25 grams*)

Shock, Burns, Trauma, Liver conditions, Cardiopulmonary Bypass Surgery

■ IVIG (Intravenous Immunoglobulin) (4 grams*)

Primary Immunodeficiencies, Secondary Antibody Deficiencies, Immune-mediated Neurological Diseases; Primary Thrombocytopenic Purpura; Other Autoimmune Diseases

■ Alpha-I Antitrypsin (.15 to .30 grams*)

Alpha-I Antitrypsin Deficiency (Genetic COPD)

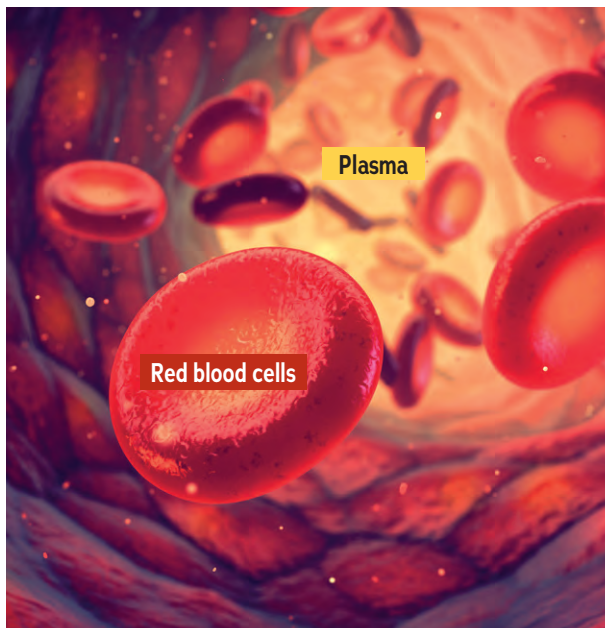
■ Coagulation Factors (Factor VIII: 300 to 450 IUs, Factor IX: 180 to 200 IUs*)

Haemophilia A & B, von Willebrand Disease, other Bleeding Disorders

* Plasma Protein Yields per Liter of Plasma

What is plasma?

Plasma is the liquid part of human blood. Some 55% of blood is plasma, the remaining 45% is composed of red blood cells, white blood cells and platelets that are suspended in the plasma. Plasma is 92% water, it contains 7% of vital proteins such as albumin, globulins, coagulation factors, and 1% mineral salts, sugars, fats, hormones and vitamins.



Plasma has four vital functions in the human body:

- Maintaining blood pressure and volume.
- Supplying critical proteins for blood clotting and immunity.
- Carrying electrolytes such as sodium and potassium to our muscles.
- Helping maintain a proper pH balance in the body, which supports cell function.

Plasma is:

- The single largest component of human blood, comprising about 55%, and contains water, salts, enzymes, antibodies.
- Composed of 92% water.
- A transport medium for cells and a variety of substances vital to the human body.
- Critical for a variety of functions in the body, including clotting blood, fighting diseases and other critical functions.

Plasma is the straw-coloured liquid portion of blood

comprised of water, salts, and proteins. 55% of the total blood volume is plasma. Due to its unique biological composition, it cannot be prepared synthetically.

55% OF TOTAL BLOOD VOLUME IS PLASMA



Plasma protein therapies are medicines made from donated plasma.

These therapies are used to treat a number of rare, chronic, conditions including primary immunodeficiencies, chronic inflammatory demyelinating polyneuropathy, hereditary angioedema, alpha-1 antitrypsin deficiency, and bleeding disorders such as haemophilia.



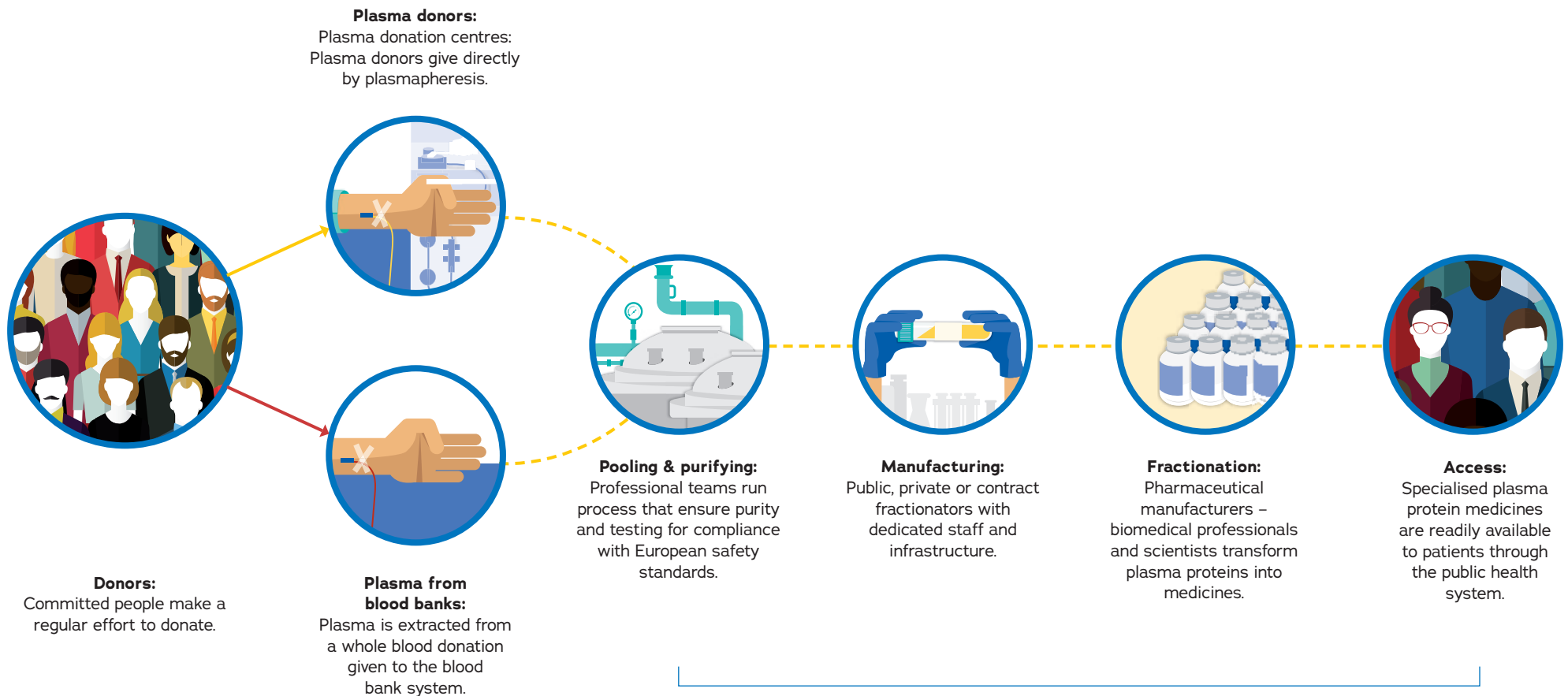
Plasma donation

Plasma is donated in two ways:

- **Direct donation by plasmapheresis**, is a process, that removes plasma (source plasma) from the donor's blood and returns the remaining cellular components to them. This is done at a specialised plasma donation centre or blood centre. Donating plasma takes 45 minutes and can be done more frequently than blood donation, **20-60 times yearly**, depending on national legislation. One plasma donation gives 650-880ml.
- **Separated from whole blood** through a whole blood donation at the national blood bank system. After donation blood is separated in its different components (recovered plasma). A whole blood donation takes about 10 minutes and can be done between **4-6 times per year** depending on gender). One whole blood donation of 500ml gives some 250-300ml of plasma.

	Extraction	Donation	Frequency	Duration	Volume
SOURCE PLASMA		 Plasma plasmapheresis	 1 x weekly	 90 min	 ~820ml
RECOVERED PLASMA		 Blood blood donation	 4-6 x yearly	 30 min	 ~250ml

The manufacturing process of plasma-derived medicines



Conditions treated by plasma-derived medicines

THERAPY	CONDITIONS TREATED	TREATMENT OUTCOMES
Coagulation factors Essential for blood clotting need, used to treat genetic bleeding disorders and surgical bleeding.	<ul style="list-style-type: none"> Bleeding from trauma Over-dosage of anticoagulants Liver disease Bleeding disorders <ul style="list-style-type: none"> Bleeding disorders of genetic origin with impaired clotting Haemophilia A & B – rare disorders Von Willebrand disease – the most common bleeding disorder 	<ul style="list-style-type: none"> Improved quality of life Increased life span
Immunoglobulines Proteins inactivating infectious agents such as bacteria and viruses and regulating immune system function. Proteins protecting body from infections caused by viruses and bacteria and regulating immune system function.	Immunodeficiencies <ul style="list-style-type: none"> Primary – Life-threatening genetic defect that compromises the immune system Secondary – Caused by infections, cancer treatments, certain medications Auto-immune diseases Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) A rare disorder of the peripheral nerves.	<ul style="list-style-type: none"> Improved quality of life Increased life-expectancy Infection prevention
Hyper-immune globulines Prevention and treatment of specific infections and medical conditions.	<ul style="list-style-type: none"> Rabies, tetanus, hepatitis and other infections Rh negative pregnancy and hemolytic disease of the newborn 	<ul style="list-style-type: none"> Prevention Treatment Protection of babies in utero
Alfa1-Protease Inhibitors Protecting lung tissue from damaging effect by enzymes of inflammatory cells.	Alfa1-Antitrypsin Deficiency Disorder caused by the genetic defect that results in liver disease and life-threatening lung damage.	<ul style="list-style-type: none"> Improved quality of life Decreased mortality and morbidity Increased life span
Albumin The major plasma protein, regulating blood volume and providing essential functions.	<ul style="list-style-type: none"> Fluid therapy Major surgeries Severe live disease Severe infections Septic shock Severe burns 	<ul style="list-style-type: none"> Lifesaving in severe situations Decreased morbidity and mortality Increased life span
C1-esterase Inhibitor	Hereditary angioedema	<ul style="list-style-type: none"> Improved quality of life Decreased mortality