

Safety of donors

Donor health

Donor health and safety is of paramount importance to the plasma industry. Only with the commitment of healthy plasma donors can high quality and safe plasma-derived medicinal products (PDMPs) be manufactured.

Is donating plasma safe?

- Donating plasma is safe!
- The safety of people who donate plasma is tracked by the Safety of Intensive Plasmapheresis studies (SIPLA I 2003; SIPLA II 2013), and further European donor safety studies, detailing several million donor experiences (PPTA 2016; 2018).
- Few plasma donors have iron depletion and it is not higher in frequent donors. Frequent plasma donation does not adversely impact iron stores.¹
- Adverse event rates for source plasma donors are rare at 15.85 per 10,000 donations,² which represents a low risk to donors, similar to blood donation.³

Who can donate plasma?

All healthy people that fulfil the relevant donor eligibility criteria can donate plasma. **Donor eligibility and deferral criteria are laid down in national and EU legislation.** These include a minimum and maximum age (18 to 60) and weight (50-150 kg), as well as a requirement to pass appropriate medical screening (tests for biochemical parameters such as haemoglobin, protein, specific cellular blood components, etc.) and to test negative for a range of pathogens that may be transmitted through transfusion, such as HIV, HCV, HBV). Additionally, **individual EU Member States may impose certain other requirements to ensure the health of the donor.**

Who is eligible to donate plasma?

DONORS MUST ...

-   **BE 18-60 YEARS OLD**
-   **BE 50-150 KG**
-   **BE IN GOOD PHYSICAL & MENTAL HEALTH**
-   **BRING PROOF OF RESIDENCE**
-   **BRING A VALID ORIGINAL PHOTO ID WITH YOU**

Examples of donor frequency as regulated by national legislative bodies

 Austria	Up to 50x yearly
 Belgium	Every 2 weeks, no more than 23x yearly
 Czech Republic	One donation every 2 weeks
 Germany	Up to 60x yearly
 Hungary	Maximum 33 donations yearly, and 1 whole blood donation per year before giving plasma

Visit to a plasma centre – from plasma to medicine

1 Booking an appointment



Donor will be asked to bring a valid official photo ID and a confirmation of his/her place of residence for his/her visit at the plasma centre.

2 Before donating

It is recommended that the donor comes prepared for the donation by:

- Eating plenty of low-fat food
- Refraining from exercising right before the donation
- Drinking a lot of water
- Getting enough of sleep

3 At the reception desk



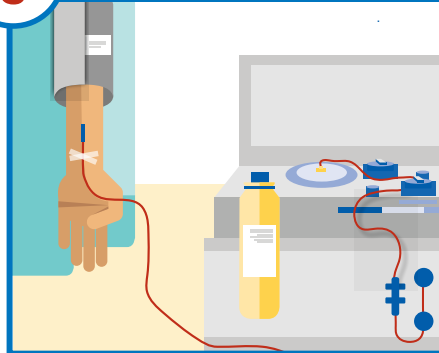
The donor is welcomed at the reception desk. The plasma donation procedure is explained to him/her. The donor completes a questionnaire about his/her health status.

4 Medical check-up



A doctor examines the donor thoroughly before the first donation. A detailed anamnesis interview is conducted with the doctors. The health check will determine whether the donor is currently suitable as a plasma donor.

5 The donation



6 After donation



It is recommended that the donor take a few minutes to rest and have something to drink after the donation.

Donor adverse events

A further study by PPTA analysed adverse events over millions of plasma donations tracked across plasma protein therapy producers.⁴ It found that the **majority of donor adverse events observed were mild and the need for medical intervention was rare.**

2021: Adverse events among U.S. source plasma donors

Data collection period	4 months
Total plasma donations	12,183,183 donations from 1.1 million donors
Adverse events	15.85 per 10,000 donations (0.16%)

About PPTA

The Plasma Protein Therapeutics Association is the global industry trade association with a strong European presence representing the private sector manufacture of plasma-derived medicinal products (PDMPs) and privately-owned plasma donation centres, including more than 160 centres in Europe. PPTA is steadfast in its mission to promote the availability of and access to safe and effective plasma protein therapies for patients worldwide.

References

- 1 Schreiber GB, Brinser R, Rosa-Bray M, Yu ZF and Simon T (2018) Frequent source plasma donors are not at risk of iron depletion: the Ferritin Levels in Plasma Donor (FLIPD) study. *Transfusion*, 58: 951-958. <https://pubmed.ncbi.nlm.nih.gov/29520799/>
- 2 Schreiber GB, Becker M, Fransen M, Hershman J, Lenart J, Song G, et al. 2021. "Plasmavigilance - Adverse events among US source plasma donors." *Transfusion* 2941-57. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/trf.16612>.
- 3 Cho J, Hiskey M. 2021. "Plasmavigilance: Source plasma joins the call to arms." *Transfusion* 2803-2805.
- 4 Idem reference 2.