ELLANN® HEALTH

INFORMATION ON INUSPHERESE®

Dear patient (f/m/d),

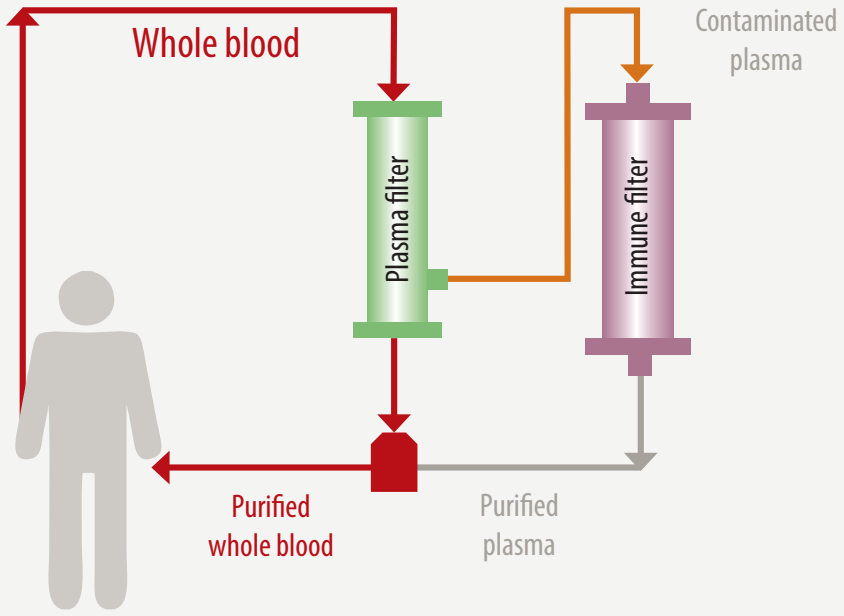
Due to a special medical situation (e.g. failure of previous therapy, rare and severe metabolic and/or autoimmune disease/treatment of last resort, desired therapy), INUSpherese® has been suggested for you by your doctor as a **healing and treatment attempt**. This means that while the procedure is known, it has not been recognized as medically necessary for the illness for which we are using it in your case. The treatment attempt is not authorized for recognition by an insurance provider.

According to the code of professional conduct and for insurance law reasons, information about the procedure and side effects of this therapy must be provided 24 hours before treatment.

Procedure:
INUSpherese® is a double-membrane filtration apheresis. The procedure itself has been used worldwide as a medical treatment for 25 years. Especially adapted equipment and a filter system adapted to your specific situation are used for INUSpherese®. The crucial point is that pathological factors are removed from the blood plasma by this special filter. The percentage removed varies among individuals.

Course of the treatment:
The blood is extracted from 2 arm veins and continuously supplied by a blood pump to what is called a plasma filter, which separates the pathologically altered plasma at a 3:1 ratio (3 parts blood to 1 part plasma by volume). A plasma pump transports the extracted plasma to a special filter (here: immune filter). The immune filter has the special characteristic of identifying pathological components/proteins and removing them from the plasma (filtration). Typically the filter fibers become discolored in the process and the pressure in the fibers increases. When the pressure in the filter fibers reaches a certain level, the proteins are flushed into a bag. This retained material is available for laboratory analyses. Blood clotting has to be temporarily inhibited for the duration of the treatment, which takes 2 to 2.5 hours depending on the individual plasma volume. To achieve this, the medication Heparin® is added to the system at the start of INUSpherese®. The dosage of the medication is precisely calculated for you so that the effect of the medication is more than 80% reversed at the end of the treatment.

Diagram of
immune filtration apheresis



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SIDE EFFECTS:

The following effects may occur due to the fact that this is an "extracorporeal" (= outside the body) procedure:

1. Dizziness and drop in blood pressure, rarely cardiac arrhythmia
2. Secondary bleeding from the puncture sites
3. Bruising at the puncture sites
4. Injury of a skin or arm nerve
5. Allergic reaction to the blood thinner Heparin®
6. Allergic reaction to foreign material (rare: 1:1,000,000)

The following steps have been/will be taken to largely avoid the aforementioned side effects:

Regarding 1.: As blood is taken from the arm veins, physiological saline solution is simultaneously infused, and all hose systems of the equipment are prefilled with saline solution, so a volume shift due to blood loss is compensated at a 1:1 ratio. A drop in blood pressure, dizziness and cardiac arrhythmia rarely occur with this procedure (less than 1:1000). An ECG is always recorded prior to INUSpherese® in order to document the heart rhythm and any changes, for example, due to known heart disease, diabetes or high blood pressure. During the treatment, circulation is also monitored continuously with a cardiovascular monitor, including blood pressure, pulse and ECG monitoring.

Regarding 2.: This complication is more likely to occur with poor vascular conditions. After the end of INUSpherese®, the needles in the arm veins are removed by the doctor or qualified personnel and an appropriate dressing is applied.

Regarding 3.: Bruising may occur despite these precautions, especially with poor vascular conditions (e.g. diabetes). You will not be discharged after treatment until the puncture wounds are closed and have been checked by the doctor/nursing staff.

Regarding 4.: This is a very rare complication, usually caused by an atypical anatomy of the nerve path. Prior to a puncture, the vascular conditions and anatomy are studied by a doctor in the course of a pre-examination and the puncture sites are established.

Regarding 5.: This complication is also rare. The symptoms are: Itching, redness of the skin. If you notice such symptoms during and after the treatment (even if you are already at home), please report them to your doctor or the nursing staff. The reaction subsides after a few hours. Please inform us now if you have a known intolerance. This information is important to us in order to optimize your treatment.

Regarding 6.: This is a very rare complication that is largely avoided thanks to today's modern production technologies for infusion needles, bandages and consumables. Itching and redness of the skin are the main symptoms. Please inform us if this occurs during or after treatment. Steps will then be taken to prevent this reaction (e.g. changing hose system lots, administering an antiallergenic if needed, using hypoallergenic materials).

GENERAL NOTES:

We rely on information regarding your medical history, current medications and known allergies (especially to medications) to successfully implement the planned INUSpherese®. Please complete the enclosed health checkup form for this purpose.
If you have any questions, please do not hesitate to contact us.
Have someone take you home on the day of the treatment because you should not operate a motor vehicle or bicycle for the next 24 hours.

☐ **Medical notes:** _____

☐ **I have understood everything** and expressly consent to the treatment attempt, even if medical necessity has not been recognized.

☐ **I still have questions:** _____

Place / date: _____ Signature of the patient or guardian: _____

Place / date: _____ Signature of the doctor providing information: _____

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