



Precaution for use

Before starting GMA treatment, your doctor will ensure that you do not find yourself in a situation that contraindicates its use, at least temporarily, or requires special precautions.

- In particular, a correct venous pathway should be ensured that can support apheresis.
- Then, precautions should be taken for patients who have or seem to have concomitant infections insofar as apheresis can aggravate their symptoms.
- Precautions should be taken for patients with heparin hypersensitivity (anticoagulant).
- Precautions should be taken for patients with a low level of erythrocytes (count lower than 300×10^4 erythrocytes/mm³), severe dehydration (count higher than 600×10^4 erythrocytes/mm³), or blood hypercoagulability (fibrinogen below 700 mg/dl). Apheresis treatment must not be started before these values have normalised.
- Precautions should be taken with patients experiencing body temperature over 38°C.
- If you have experienced body temperature (fever) before the GMA session, contact your doctor. It would be better to delay it until resolution.
- Apheresis treatment can be performed on patients receiving angiotensin-converting enzyme inhibitors (ACE). If you are taking ACEs, suspend treatment at least 24h before the GMA session. Blood pressure and heart rate must be closely monitored during this treatment.
- The doctor must carefully assess the benefits of apheresis treatment in terms of potential risks for patients with liver, kidney or severe cardiovascular disease.

PLEASE DO NOT HESITATE TO CONTACT YOUR GP AND/OR YOUR GASTROENTEROLOGIST FOR ANY FURTHER INFORMATION.

The strict consistency of every treatment is often needed for them to be effective.

Please do not hesitate to talk to your doctor if you are experiencing any difficulties in this area.

For healthcare professionals use only



GRANULOCYTE AND MONOCYTE APHERESIS IN IBD

GRANULOCYTE AND MONOCYTE APHERESIS (GMA) in IBD

This leaflet aims to better inform the patient about GMA apheresis treatment used in chronic inflammatory diseases like Inflammatory Bowel Disease (IBD, Ulcerative colitis, Crohn's Disease). It takes specific conditions of use into account in these diseases.

What is is GMA?

Apheresis is an extracorporeal blood purification procedure. There are several types of apheresis depending on the type of purification target (leukapheresis, plasmapheresis, LDL apheresis, etc.).

GMA apheresis is intended for treating patients with autoimmune disorders or chronic inflammatory disease. It enables the selective adsorption of granulocytes and monocytes/macrophages from the peripheral blood.

Indications and effectiveness

Apheresis is a non-drug therapeutic alternative for treating rheumatoid arthritis. The principle of this procedure is to collect the white blood cells responsible for the inflammation from activated proinflammatory granulocytes and the peripheral blood via adsorption of granulocytes and monocytes/macrophages, and to remove them from the bloodstream so as to decrease the induced inflammation in these diseases.

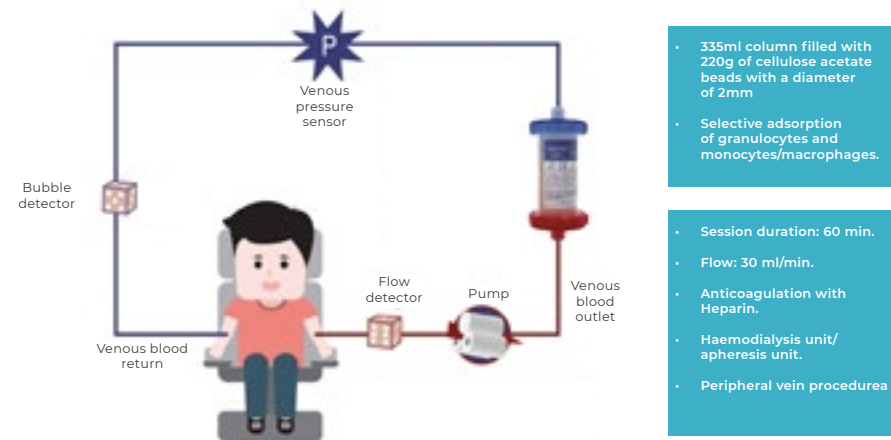
Tolerance and effectiveness

The apheresis device's tolerance and effectiveness has been studied for the treatment of a number of diseases, including ulcerative colitis, Crohn's disease, rheumatoid arthritis, systemic lupus erythematosus, Behçet's eye disease and pustular psoriasis.

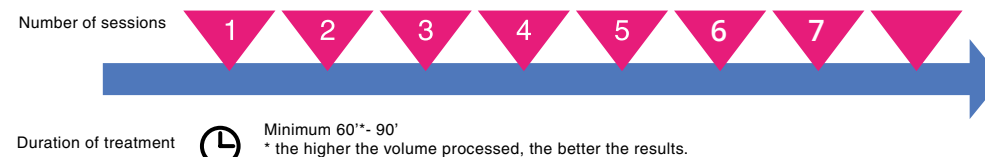
The cells or proteins involved in the pathogenesis of these diseases are held back by the apheresis device. This removal of blood cells or plasma components is associated with minor side effects. Apheresis is therefore considered a useful treatment for chronic autoimmune disorders, avoiding or reducing the use of drug therapies that, in some cases, can lead to serious side effects.

Conditions of use

After the blood is extracted, preferably through one of the antecubital veins, and passes through the circuit and the ADACOLUMN® filter, it is re-infused into the patient through one of the contralateral antecubital veins.



The recommended treatment regimen is: 2 sessions a week during at least the first 2-3 weeks. In case of it not being possible to follow the recommended option, perform: one session a week for 8-10 consecutive weeks.



Flow: 30 ml/min
Total volume of treated blood: 1.8 L or more
Minimum of 1800 ml* (>=35% total blood volume).

Storage conditions: 1-30°C
Single-use. Do not reuse.

- The extracorporeal volume is around 220 ml and circulates through the device at a rate of 30 ml/min.
- Anticoagulant therapy is necessary during apheresis, usually with heparin administered, either via intravenous bolus or continuous infusion.
- Apheresis is performed via simple venous cannulation.
- It is advisable to perform arm exercises (with weight or tensors) some days prior to the GMA session to improve venous circulation.
- It is important to ingest enough liquids some hours before the GMA session to ensure good hydration.
- Avoid unnecessary blood extractions during this period.
- Wear comfortable, short-sleeved clothing.
- Avoid activities with a high risk of traumatism for 12 to 24 h after the GMA session.



Medical follow-up and risk of side effects

During treatment, you will be monitored by your doctor who will decide whether any monitoring test need to be performed.

The most commonly recorded side effects are: hypotension, palpitations, redness, fatigue, malaise, headache, vertigo, nausea, vomiting, increased blood pressure, haemolysis, haematuria, cough, abdominal pain, chest pain, urticaria, lower back pain, back pain, dyspnoea, burning sensation, paraesthesia, muscle spasms, watering eyes, pruritus, redness at injection site, anaphylactic shock/symptoms, and other signs and symptoms were reported as side effects that are commonly caused by extracorporeal circulation.

If abnormal reactions occur, GMA must be stopped immediately and suitable corrective measures must be taken.

A special precaution is required for patients with severe peripheral venous embolism. Some isolated cases of thrombocytopenia (reduced number of platelets in the blood) were observed, all of which occurred whilst using heparin.

Precaution during pregnancy

In the absence of studies on the safety of using leukocyte apheresis during pregnancy or whilst breast-feeding, it must be only be used for pregnant women if absolutely necessary and the interruption of breast-feeding throughout the period in which the mother shall be treated by apheresis should be considered.