Package leaflet: Information for the patient

GAMMA anty-D 150, 150 micrograms/ml
Solution for injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GAMMA anty-D 150 is and what it is used for

GAMMA anty-D 150 is a solution of human immunoglobulins G that contains 150 micrograms (750 IU) of anti-D (anti-Rh) antibodies.
The prophylaxis of haemolytic disease of the newborn (HDN) with the product GAMMA anty-D 150 consists of the suppression of the immunological response to antigen D present in the blood cells of the foetus in an Rh-negative woman.
Administration of GAMMA anty-D 150 prevents anti-D (anti-Rh) antibodies formation in a female body when approx. 7 ml of Rh+ (positive) blood cells have entered woman`s bloodstream. In the case of a Rh(D) positive foetus, the presence of anti-D antibodies may be a factor threatening the children's health.
The product is administered within 72 hours after delivery and prevents production of anti-D antibodies, which consequently prevents the occurrence of haemolytic disease of the newborn (HDN) in a future pregnancy.
When administered in the 28th week of the pregnancy, the product prevents production of anti-D antibodies during 12 weeks before delivery. The product is also administered after the abortion of a foetus after the 12th week of gestation, in the threat of immature or premature labour, and after diagnostic amniocentesis after the 12th week of pregnancy. GAMMA anty-D 150 is not effective if production of antibodies in the mother's body has already been stimulated. For this reason, product administration to women with anti-D antibodies is pointless.

2. What you need to know before you use GAMMA anty-D 150

Do not use GAMMA anty-D 150:
Before administration, the following serological tests should be performed:
- qualification of the group AB0 and Rh in a woman, and after birth also in an infant,

- anti-D antibodies in the serum of a woman,
- antiglobulin test on the child's blood cells immediately after the birth.

The physician should ask, and a woman should provide full information about:
- past allergic reactions to human immunoglobulin and any other substances such as: foods, preservatives and other,
- past serious diseases, especially immune deficiencies.
    - Do not administer intravenously.
    - Do not administer to newborn infants.
    - Do not administer to Rh+ (positive) (D+) women.
    - If you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using GAMMA anty-D 150.

Hypersensitivity

True hypersensitivity reactions are rare but allergic type responses to anti-D immunoglobulin may occur.

The patient should be observed for at least 20 minutes after administration.

GAMMA anty-D 150 contains a small quantity of IgA. Although anti-D immunoglobulin has been used successfully in selected IgA deficient individuals, individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of plasma derived medicinal products containing IgA. The physician must therefore weigh the benefit of treatment with GAMMA anty-D 150 against the potential risks of hypersensitivity reactions.

Rarely, human anti-D immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who have tolerated previous treatment with human immunoglobulin. Patients should be informed of the early symptoms of hypersensitivity reaction, including rash, generalised urticaria, tightness of the chest, pressure drop, wheezing and anaphylaxis. The treatment depends on the cause and severity of the side effect. Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented.

Haemolytic reactions

Patients in receipt of incompatible transfusion, who receive very large doses of anti-D immunoglobulin, should be monitored clinically and by biological parameters.

GAMMA anty-D 150 is derived from human plasma collected from donors with a high level of anti-D antibodies.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). However, they can have a limited efficiency for non-enveloped viruses, such as virus of hepatitis A (HAV) and/or parvovirus B19.

There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins. It is also assumed that the antibody content makes an important contribution to the viral safety.

It is strongly recommended that every time that GAMMA anty-D 150 is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Other medicines and GAMMA anty-D 150
Tell your doctor if you are using, have recently used or might use any other medicines. The product may impair efficiency of vaccines containing live attenuated viruses, i.e. measles, rubella, mumps. The administration of immunoglobulin should be followed by a 3-month pause before such vaccinations.
If any laboratory tests are performed, tell your doctor about taking immunoglobulins, because this may affect the results of serological tests.

Pregnancy and breast-feeding
This medicinal product is used in pregnancy and during breastfeeding.

Fertility
If you are planning to have a baby, ask your doctor for advice before taking this medicine. No animal fertility studies have been conducted with GAMMA anty-D 150. Clinical experience with human anti-D immunoglobulin suggests that no harmful effects on fertility are to be expected.

Driving and using machines
GAMMA anty-D 150 has no influence on the ability to drive and use machines.

3. How to use GAMMA anty-D 150

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
GAMMA anty-D 150 is administered intramuscularly.
Do not administer intravenously.
The recommended dosage is:
The product should be administered intramuscularly within 48 hours, 72 hours at the latest, in the following cases:

- 1 dose (150 micrograms) is used after a physiological birth, after the abortion of a foetus after the 12th week of gestation, in the threat of immature or premature labour and after diagnostic amniocentesis after the 12th week of pregnancy,
- 2 doses (300 micrograms) after a pathological birth, e.g. CS, manual placenta removal, stillbirth,
- 2-3 doses (300-450 micrograms) after foetal exsanguination to the mother's bloodstream (it is recommended that the size of the transplacental leak is determined and adequate dose established),
- after a multiple birth the number of doses is the same as the number of children.

The medicine is used in pregnant women:

- 2 doses (300 micrograms) once to Rh-negative women in the 28th week of pregnancy, for whom anti-D antibodies cannot be detected.

The medicine should be administered in an intramuscular injection by a doctor or nurse. The product should be brought to room or body temperature before use. The doctor or nurse should check whether the solution in an ampoule is transparent or slightly opalescent.
Do not use solutions that are cloudy or have deposits. Any unused product or waste material should be disposed of in accordance with local requirements.

If coagulation impairment occurs, when intramuscular administration is contraindicated, GAMMA anty-D 150 can be administered subcutaneously. Protect the injection site by manual pressure with a swab.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Undesirable effects may occur even if the patient has previously taken immunoglobulins and tolerated them well.

Side effects such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally. Rarely human immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.
Local reactions at infusion sites: swelling, soreness, redness, induration, local heat, itching, bruising, rash.

The following side effects were rare (concerns 1 to 10 in 10,000 patients):
headache, skin reactions, fever, malaise, chills.

The following side effects were very rare (concerns less than 1 in 10,000 patients):
allergic reactions and anaphylactic reactions (dyspnea and symptoms of anaphylaxis), tachycardia, fall in blood pressure, nausea, vomiting.

Frequency of the following side effects is not known (cannot be estimated from the available data):
redness, itching, arthralgia, at administration site: swelling, soreness, tenderness, redness, induration, warmth, pruritus, rash.

In case of any symptoms of anaphylactic shock (headache and dizziness, swelling of the lips and tongue, pallor, urticaria, fall in blood pressure, abnormal heart rhythm, dyspnoea, vomiting, diarrhoea, convulsions, loss of consciousness) contact physician without delay for immediate medical attention.

For safety information with respect to transmissible agents, see section 2.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products: Al. Jerozolimskie 181C, 02-222 Warszawa, Phone: 22 49-21-301, Fax 22 49-21-309, web page: https://smz2.ezdrowie.gov.pl.
Adverse reaction can be also reported to marketing authorization holder.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store GAMMA anty-D 150

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the packaging.
The expiry date refers to the last day of that month.
Store in a refrigerator (2°C - 8°C).
Keep away from light.

Do not throw away any medicines via wastewater or household waste.
Ask your pharmacist how to throw away medicines you no longer use.
These measures will help protect the environment.
Batch number (Lot)
Expiry date (EXP)

6. Contents of the pack and other information

What GAMMA anty-D 150 contains

- The active substance is human anti-D immunoglobulin, 150 micrograms (750 IU)/ml
- The other excipients are: glycine, sodium chloride, water for injections

What GAMMA anty-D 150 looks like and contents of the pack
The medicine is transparent or slightly opalescent solution for injection.

A single pack contains 1 ampoule of 1 mL

Marketing Authorisation Holder and Manufacturer

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