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**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
(CPMP)**

**CORE SPC FOR HUMAN ANTI-D IMMUNOGLOBULIN FOR
INTRAVENOUS AND/OR INTRAMUSCULAR USE**

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**CORE SPC
FOR
HUMAN ANTI-D IMMUNOGLOBULIN FOR INTRAVENOUS AND/OR
INTRAMUSCULAR USE**

The EMEA template for Summary of Product Characteristics and the QRD convention provide general guidance on format and text and should be read in conjunction with the core SPC and the Guideline on Summary of Product Characteristics.

QRD convention to be followed for EMEA templates
Product information template with explanatory notes

The following convention is used in this core SPC:
- <wave-underlined text> for intramuscular immunoglobulin
- <dot-underlined text> for intravenous immunoglobulin

1. NAME OF THE MEDICINAL PRODUCT

{(Trade) name of product <strength> <pharmaceutical form>}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Human Anti-D immunoglobulin>

[*Product Specific information on quantitative composition. Include: human protein content, maximum IgA content.*]

For excipients, see 6.1

3. PHARMACEUTICAL FORM

[*Product specific*]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of Rh(D) immunisation in Rh(D) negative women

- Pregnancy/delivery of a Rh(D) positive baby
- Abortion/threatened abortion, ectopic pregnancy or hydatidiform mole
- Transplacental haemorrhage (TPH) resulting from ante-partum haemorrhage (APH), amniocentesis, chorionic biopsy or obstetric manipulative procedures e.g. external version, or abdominal trauma.

Treatment of Rh(D) negative persons after incompatible transfusions of Rh(D) positive blood or other products containing red blood cells.

[*Other product specific indications*]

4.2 Posology and method of administration

Posology

[*Product specific*]

For postnatal use, the product should be administered as soon as possible within 72 hours of delivery. If a large foeto-maternal haemorrhage is suspected, its extent should be determined by a suitable method and additional doses of anti-D should be administered as indicated.

Method of administration

<For intramuscular use.

In case of haemorrhagic disorders where intramuscular injections are contraindicated, Anti-D immunoglobulin may be administered subcutaneously. Careful manual pressure with a compress should be applied to the site after injection.

If large total doses (> 5 ml) are required, it is advisable to administer them in divided doses at different sites.>

<For intravenous use administered by slow injection.>

4.3 Contraindications

Hypersensitivity to any of the components.

4.4 Special warnings and special precautions for use

<Do not inject this product intravenously (risk of shock).>

In the case of postpartum use, the product is intended for maternal administration. It should not be given to the new-born infant.

The product is not intended for use in Rh(D) positive individuals.

Patients should be observed for at least 20 minutes after administration.

If symptoms of allergic or anaphylactic type reactions occur, immediate discontinuation of the administration is required.

True hypersensitivity reactions are rare but allergic type responses to Anti-D immunoglobulin may occur. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. The treatment required depends on the nature and severity of the side effect. In case of shock, the current medical standards for shock treatment should be observed.

[Product specific]

<{Tradename of the product} contains a small quantity of IgA. Although anti-D immunoglobulin has been used successfully to treat selected IgA deficient individuals, the attending physician must weigh the benefit against the potential risks of hypersensitivity reactions. Individuals deficient in IgA have a potential for development of IgA antibodies and anaphylactic reactions after administration of blood components containing IgA.>

[The choice of text indicated between <> depends on whether inactivation/removal procedures in the production process are effective for the specified virus.]

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to transmission of infective agents cannot be totally excluded. This also applies to pathogens of unknown nature. The risk of transmission of infective agents is however reduced by:

- selection of donors by a medical interview and screening of individual donations and plasma pools for HBsAg and antibodies to HIV and HCV.
- testing of plasma pools for HCV genomic material.
- inactivation/removal procedures included in the production process that have been validated using model viruses. These procedures are considered effective for HIV, HCV <, HAV><, parvovirus B19> and HBV.

<The viral inactivation/removal procedures may be of limited value against non-enveloped viruses such as <HAV > <and/or> parvovirus B19.>

In the interest of patients, it is recommended that, whenever possible, every time that {name of the product} is administered to them, the name and batch number of the product is registered.

4.5 Interactions with other medicinal products and other forms of interactions

Active immunisation with live virus vaccines (e.g. measles, mumps or rubella) should be postponed until 3 months after the last administration of anti-D immunoglobulin, as the efficacy of the live virus vaccine may be impaired.

If anti-D immunoglobulin needs to be administered within 2-4 weeks of a live virus vaccination, then the efficacy of such a vaccination may be impaired.

After injection of immunoglobulin the transitory rise of the various passively transferred antibodies in the patients blood may result in misleading positive results in serological testing.

The results of blood typing and antibody testing including the Coombs or antiglobulin test, are significantly affected by the administration of anti-D immunoglobulin.

4.6 Pregnancy and lactation

This medicinal product is used in pregnancy.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

<Local pain and tenderness can be observed at the injection site; this can be prevented by dividing larger doses over several injection sites.>

Occasionally fever, malaise, headache, cutaneous reactions and chills occur. In rare cases: nausea, vomiting, hypotension, tachycardia, and allergic or anaphylactic type reactions, including dyspnoea and shock, are reported, even when the patient has shown no hypersensitivity to previous administration.

For information on viral safety see 4.4.

4.9 Overdose

No data are available on overdosage. Patients with incompatible transfusion who receive an overdose of Anti-D immunoglobulin, should be monitored clinically and by biological parameters, because of the risk of haemolytic reaction.

In other Rh(D) negative individuals overdosage should not lead to more frequent or more severe undesirable effects than the normal dose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: immune sera and immunoglobulins: Anti-D (Rh) immunoglobulin. ATC code: J06BB01.

Anti-D immunoglobulin contains specific antibodies (IgG) against the D (Rh) antigen of human erythrocytes.

5.2 Pharmacokinetic properties

<Measurable levels of antibodies are obtained approximately {x} hours after intramuscular injection. Peak serum levels are usually achieved {x} days later.>

<Measurable levels of antibodies are obtained immediately after intravenous injection.>

The half-life in the circulation of individuals with normal IgG levels is {x} weeks.

IgG and IgG-complexes are broken down in cells of the reticuloendothelial system.

5.3 Preclinical safety data

[Product specific]

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[Product specific. Where applicable, the amount of albumin added as a stabiliser should be stated (Ph. Eur. labelling requirement).]

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products.

[Product specific]

6.3 Shelf-life

[Product specific]

6.4 Special precautions for storage

[Product specific]

6.5 Nature and contents of container

[Product specific]

6.6 Instructions for use and handling and disposal

[Product specific]

The product should be brought to room or body temperature before use.

<Total reconstitution should be obtained within [product specific time].>

The solution should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits. *<Reconstituted products should be inspected visually for particulate matter and discoloration prior to administration.>*

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

{Name and address }

8. MARKETING AUTHORISATION NUMBER(S)

[Product specific]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[Product specific]

10. DATE OF REVISION OF THE TEXT

[Product specific]