SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Haemoctin 250
Haemoctin 500
Haemoctin 1000

Powder and solvent for solution for injection
Human plasma derived coagulation factor VIII

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains 250, 500 or 1000 IU human plasma derived coagulation factor VIII.
Haemoctin 250 or Haemoctin 500 contains approximately 50 IU/ml human coagulation factor VIII when reconstituted with 5 or 10 ml of water for injections. Haemoctin 1000 contains approximately 100 IU/ml human coagulation factor VIII when reconstituted with 10 ml of water for injections.

The potency (IU) is determined using the European Pharmacopoeia chromogenic factor VIII coagulation assay. The specific activity of Haemoctin 250, 500 or 1000 is approximately 100 IU/mg protein.

Produced from the plasma of human donors.

Excipient with known effect:
One vial contains up to 32.2 mg sodium (1.4 mmol).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.
White powder and clear, colourless solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency).

Management of acquired factor VIII deficiency.

This preparation does not contain von Willebrand factor in pharmacologically effective quantities and is therefore not indicated in von Willebrand´s disease.

4.2 Posology and method of administration

Treatment should be under the supervision of a physician experienced in the treatment of haemophilia.

Treatment monitoring
During the course of treatment, appropriate determination of factor VIII levels is advised to guide the dose to be administered and the frequency of repeated infusions. Individual patients may vary in their

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response to factor VIII, demonstrating different half-lives and recoveries. Dose based on bodyweight may require adjustment in underweight or overweight patients. In the case of major surgical interventions in particular, precise monitoring of the substitution therapy by means of coagulation analysis (plasma factor VIII activity) is indispensable.

When using an *in vitro* thromboplastin time (aPTT)-based one stage clotting assay for determining factor VIII activity in patients' blood samples, plasma factor VIII activity results can be significantly affected by both the type of aPTT reagent and the reference standard used in the assay. Also there can be significant discrepancies between assay results obtained by aPTT-based one stage clotting assay and the chromogenic assay according to Ph. Eur. This is of importance particularly when changing the laboratory and/or reagents used in the assay.

Posology

The dose and duration of the substitution therapy depend on the severity of the factor VIII deficiency, on the location and extent of the bleeding and on the patient´s clinical condition.

The number of units of factor VIII administered is expressed in International Units (IU), which are related to the current WHO concentrate standard for factor VIII products. Factor VIII activity in plasma is expressed either as a percentage (relative to normal human plasma) or preferably in International Units (relative to an International Standard for factor VIII in plasma).

One International Unit (IU) of factor VIII activity is equivalent to that quantity of factor VIII in one ml of normal human plasma.

On demand treatment

The calculation of the required dose of factor VIII is based on the empirical finding that 1 International Unit (IU) factor VIII per kg body weight raises the plasma factor VIII activity by 1 % to 2 % of normal activity. The required dose is determined using the following formula:

Required units = body weight (kg) x desired factor VIII rise (%) x 0.5

The amount to be administered and the frequency of administration should always be oriented to the clinical effectiveness in the individual case.

In the case of the following haemorrhagic events, the factor VIII activity should not fall below the given plasma activity level (in % of normal) in the corresponding period. The following table can be used to guide dosing in bleeding episodes and surgery:

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Degree of haemorrhage/ Type of surgical procedure	Factor VIII level required (%)	Frequency of doses (hours)/Duration of therapy (days)
Haemorrhage		
Early haemarthrosis, muscle bleeding or oral bleeding	20 - 40	Repeat every 12 to 24 hours. At least 1 day, until the bleeding episode as indicated by pain is resolved or healing is achieved.
More extensive haemarthrosis, muscle bleeding or haematoma	30 - 60	Repeat every 12 to 24 hours for 3 - 4 days or more until pain and acute disability are resolved.
Life threatening haemorrhages	60 - 100	Repeat every 8 to 24 hours until threat is resolved.
Surgery		
Minor surgery including tooth extraction	30 - 60	Every 24 hours, at least 1 day, until healing is achieved.
Major surgery	80 - 100 (pre- and post-operative)	Repeat every 8 to 24 hours until adequate wound healing, then therapy for at least another 7 days to maintain a factor VIII activity of 30 - 60%.

Prophylaxis
For long term prophylaxis against bleeding in patients with severe haemophilia A, the usual doses are 20 to 40 IU of factor VIII per kg body weight at intervals of 2 to 3 days. In some cases, especially in younger patients, shorter dosage intervals or higher doses may be necessary.

There are insufficient data to recommend the use of Haemoctin 250, 500 or 1000 in children less than 6 years of age.

Method of administration
Intravenous use. It is recommended not to administer more than 2-3 ml Haemoctin/ min. For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability
In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity
Allergic type hypersensitivity reactions are possible with Haemoctin. The product contains traces of human proteins other than factor VIII. If symptoms of hypersensitivity occur, patients should be advised to discontinue use of the medicinal product immediately and contact their physician. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis.

In case of shock, standard medical treatment for shock should be implemented.

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Inhibitors
The formation of neutralising antibodies (inhibitors) to factor VIII is a known complication in the management of individuals with haemophilia A. These inhibitors are usually IgG immunoglobulins directed against the factor VIII procoagulant activity, which are quantified in Bethesda Units (BU) per ml of plasma using the modified assay. The risk of developing inhibitors is correlated to the severity of the disease as well as the exposure to factor VIII, this risk being highest within the first 50 exposure days but continues throughout life although the risk is uncommon.
The clinical relevance of inhibitor development will depend on the titre of the inhibitor, with low titre posing less of a risk of insufficient clinical response than high titre inhibitors.

In general, all patients treated with coagulation factor VIII products should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed. In patients with high levels of inhibitor, factor VIII therapy may not be effective and other therapeutic options should be considered. Management of such patients should be directed by physicians with experience in the care of haemophilia and factor VIII inhibitors.

Cardiovascular events
In patients with existing cardiovascular risk factors, substitution therapy with factor VIII may increase the cardiovascular risk.

Catheter-related complications
If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered.

Transmissible agents
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), and for the non-enveloped hepatitis A virus (HAV). The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19.

Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g. haemolytic anaemia).

Appropriate vaccination (hepatitis A and B) should be considered for patients in regular/repeated receipt of human plasma-derived factor VIII products.
Paediatric population
The special warnings and precautions for use mentioned for the adults should also be considered for the paediatric population.

Sodium content
This medicinal product contains up to 32.2 mg sodium (1.4 mmol) per vial, equivalent to 1.61% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions of human coagulation factor VIII products with other medicinal products have been reported.

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4.6 Fertility, pregnancy and lactation

Animal reproduction studies have not been conducted with factor VIII. Based on the rare occurrence of haemophilia A in women, experience regarding the use of factor VIII during pregnancy and breast-feeding is not available. Therefore, factor VIII should be used during pregnancy and lactation only if clearly indicated.

4.7 Effects on ability to drive and use machines

Haemoctin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the infusion site, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) have been observed rarely and may in some cases progress to severe anaphylaxis (including shock).

Development of neutralising antibodies (inhibitors) may occur in patients with haemophilia A treated with factor VIII, including with Haemoctin. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted.

For safety information with respect to transmissible agents, see section 4.4.

Tabulated list of adverse reactions
The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).
Frequencies have been evaluated according to the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).
From clinical trials, non interventional studies, spontaneous reporting and regular literature screening the following adverse reactions were reported on Haemoctin:

MedDRA Standard System Organ Class	Adverse reactions	Frequency
Blood and lymphatic system disorders	Factor VIII inhibition	uncommon (PTPs)* very common (PUPs)*
Immune system disorders	Anaphylactic shock, hypersensitivity	not known
Skin and subcutaneous tissue disorder	Erythema, pruritus, urticaria	not known

**Frequency is based on studies with all factor VIII products which included patients with severe haemophilia A. PTPs = previously-treated patients, PUPs = previously-untreated patients.*

Paediatric population
With exception of factor VIII inhibition, adverse reactions in children are expected to be the same as in adults (see table above).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

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4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: antihaemorrhagics: blood coagulation factor VIII.
ATC code: B02BD02.

The factor VIII/von Willebrand factor complex consists of two molecules (factor VIII and von Willebrand factor) with different physiological functions. When infused into a haemophiliac patient, factor VIII binds to von Willebrand factor in patient´s circulation.

Activated factor VIII acts as a cofactor for activated factor IX, accelerating the conversion of factor X to activated factor X (factor Xa). Activated factor X converts prothrombin into thrombin. Thrombin then converts fibrinogen into fibrin and a clot can be formed. Haemophilia A is a sex-linked hereditary disorder of blood coagulation due to decreased levels of factor VIII:C and results in profuse bleeding into joints, muscles or internal organs, either spontaneously or as a result of accidental or surgical trauma. By replacement therapy the plasma levels of factor VIII are increased, thereby enabling a temporary correction of the factor deficiency and correction of the bleeding tendencies.

In addition to its role as a factor VIII protecting protein, von Willebrand factor mediates platelet adhesion to sites of vascular injury and plays a role in platelet aggregation.

Data on successfully performed Immune Tolerance Induction (ITI) have been collected in patients with haemophilia A who have developed inhibitors to factor VIII.

Of note, annualized bleeding rate (ABR) is not comparable between different factor concentrates and between different clinical studies.

5.2 Pharmacokinetic properties

Plasma factor VIII activity decreases by a two-phase exponential decay after intravenous use. In the initial phase, distribution between intravascular and other compartments (body fluids) occurs with a half-life of elimination from the plasma of 1 to 8 hours. In the subsequent phase the half-life varies between 5 - 18 hours, with an average of about 12 hours. This appears to correspond to the true biological half-life.

The incremental recovery of Haemoctin is approximately 0.020 ± 0.003 IU/ml/IU/kg b.w. The level of factor VIII activity after intravenous use of 1 IU factor VIII per kg b.w. is about 2 %.

Other pharmacokinetic parameters of Haemoctin are:
- Area under the curve (AUC): about 17 IU x h / ml
- Mean residence time (MRT): about 15 h
- Clearance: about 155 ml/h.

5.3 Preclinical safety data

Human plasma coagulation factor VIII (from the concentrate) is a normal constituent of the human plasma and acts like the endogenous factor VIII. Single dose toxicity testing is of no relevance since higher doses result in overloading. Repeated dose toxicity testing in animals is impracticable due to the interference with developing antibodies to heterologous protein.

Even doses of several times the recommended human dose per kilogram body weight show no toxic effects on laboratory animals.

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Since clinical experience provides no hint for tumorigenic and mutagenic effects of human plasma coagulation factor VIII, experimental studies, particularly in heterologous species, are not considered imperative.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder: glycine, sodium chloride, sodium citrate, calcium chloride
Solvent: water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Only the provided infusion sets should be used because treatment failure can occur as a consequence of human coagulation factor VIII adsorption to the internal surfaces of some infusion equipment.

6.3 Shelf-life

2 years

6.4 Special precautions for storage

Do not store above 25 C. Do not freeze.
Keep the vials in the outer carton in order to protect from light.

After first opening, the product should be used immediately.
The solution ready for use should be used immediately after dissolving.

6.5 Nature and contents of container

1 package Haemoctin 250, 500 or 1000 contains:

1 vial with powder (20 ml) out of glass type I acc. to Ph.Eur. (current edition). Freeze-drying stoppers out of halobutyl-caoutchouc, type I acc. to Ph.Eur. (current edition).

1 vial with solvent (5 ml, 10 ml), glass type I acc. to Ph.Eur. (current edition). Injection stoppers out of halobutyl-caoutchouc, type I acc. to Ph.Eur. (current edition).

The pack also contains:
1 disposable syringe (5 ml, 10 ml), 1 transfer system with integral filter, 1 butterfly cannula.

6.6 Special precautions for disposal and other handling

Reconstituted medicinal product should be inspected visually for particulate matter and discoloration prior to administration. The solution should be clear 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.

Instructions for use and handling:
Absolute sterility is to be ensured in all steps of the procedure!

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Fig. 1a

Fig. 1b

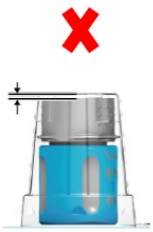

Fig. 1c

Fig. 2

Fig. 3

Fig. 4

Fig. 5

Fig. 6

Fig. 7

Fig. 8

Dissolution of the concentrate:

- Bring the unopened vials of the solvent (water for injections) and product to room temperature. If a water bath is used for warming, it must be scrupulously ensured that the water does not come into contact with the caps or stoppers of the vials. Otherwise contamination of the medicine may occur.
- **Very important** for proper use of the transfer system: prior to opening, make sure that the white lower part of the transfer system sits directly on the ground of the blister (Fig. 1a: correct/ Fig. 1b: not correct). If not correct: push the transfer system down in the blister until the white lower part of the transfer system sits directly on the ground of the blister (Fig. 1c).
- Remove the caps from the solvent and the product vial in order to expose the central portions of the rubber stoppers (Fig. 2). Ensure that the rubber stoppers of the product and solvent vials are treated with a disinfectant.
- Remove the top of the transfer system packaging (Fig. 3).
- Place the solvent vial on even surface. Place the blue part of the transfer system within the blister straight onto the upright standing vial containing the solvent (Fig. 4). Do not twist the transfer system!
- Remove the remaining part of the blister from the transfer system. Do not squeeze the blister! Now the white part of the transfer system is visible (Fig. 5).
- Place the product vial on an even surface.
- Turn the combination of transfer system and solvent vial upside down. Push the spike of the white part of the adapter straight down through the product vial stopper (Fig. 6). The vacuum present in the product vial causes the solvent to flow into the product vial.
- Gently swirling the product vial helps in dissolving the powder. Do not shake vigorously, all foaming is to be avoided! The solution is clear or slightly opalescent.
- Afterwards unscrew the blue part of the transfer system together with the solvent vial counterclockwise (Fig. 7). Discard the solvent vial with the blue part of the transfer system attached. The Luer-Lock connector is now visible.

The solution ready for use should be used immediately after dissolving. Do not use solutions that are cloudy or contain visible particles.

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Injection:

- Once you have dissolved the powder as described above, screw the enclosed syringe onto the Luer-Lock connector of the product vial with the white part of the transfer system (Fig. 8). This allows you to easily draw the dissolved drug into the syringe. A separate filter is not necessary because the transfer system has its own integral filter.
- Carefully disconnect the vial with the white part of the transfer system from the syringe. Use the enclosed butterfly needle and administer immediately by slow intravenous injection. The injection rate must not exceed 2-3 ml/minute.
- After the butterfly needle has been used, it can be made safe with the protective cap.

7. MARKETING AUTHORISATION HOLDER

PT Kimia Farma Tbk. - Jakarta, Indonesia

8. MARKETING AUTHORISATION NUMBER(S)

- Box, 1 vial with powder (250 IU) + 1 vial with water for injections (5 ml) + 1 disposable syringe + 1 transfer system with integral filter + 1 butterfly cannula. DKI1226000344A1
- Box, 1 vial with powder (500 IU) + 1 vial with water for injections (10 ml) + 1disposable syringe + 1 transfer system with integral filter + 1 butterfly cannula. DKI1226000344A1
- Box, 1 vial with powder (1000 IU) + 1 vial with water for injections (10 ml) + 1disposable syringe + 1 transfer system with integral filter + 1 butterfly cannula. DKI1226000344B1

9. DATE OF FIRST AUTHORISATION

28. MAY 2012

10. DATE OF REVISION OF THE TEXT

11/2025

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.

Namun pada produk jadi tidak ditemukan adanya DNA babi.

To report an adverse event or product quality complaint, please contact:
Pharmacovigilance Center of PT Kimia Farma Tbk.
Email: pv@kimiafarma.co.id Phone: (021) 1500 255

Manufactured by:
Biotest AG
Landsteinerstrasse 5, 63303 Dreieich
Germany

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Released by:
Biotest Pharma GmbH
Landsteinerstrasse 5, 63303 Dreieich
Germany
Phone: +49 6103 801-0
Fax: +49 6103 801-150
Email: mail@biotest.com

Imported by:

PT Kimia Farma Tbk.
Jl. Rawagelam V No. 1
Kawasan Industri Pulogadung
Jakarta, Indonesia 13930

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Brosur kemasan: Informasi untuk pengguna

Haemoctin 250

Haemoctin 500

Haemoctin 1000

Bubuk dan pelarut untuk larutan injeksi

Faktor koagulasi VIII yang berasal dari plasma manusia

Baca seluruh isi Brosur ini dengan seksama sebelum Anda mulai menggunakan obat ini karena Brosur ini berisi informasi penting untuk Anda.

- Simpan Brosur ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan untuk Anda. Jangan berikan obat ini kepada orang lain. Obat ini dapat membahayakan mereka, meskipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping, konsultasikan dengan dokter, apoteker, atau perawat Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam Brosur ini. Lihat bagian 4.

Brosur ini berisi:

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3. Cara menggunakan Haemoctin

4. Kemungkinan efek samping

5. Cara menyimpan Haemoctin

6. Isi kemasan dan informasi lainnya

1. Definisi Haemoctin dan kegunaannya

Haemoctin adalah obat yang berasal dari plasma manusia. Obat ini mengandung faktor koagulasi VIII, yang diperlukan untuk pembekuan darah normal. Setelah bubuk dicampur dengan air untuk injeksi, larutan siap untuk injeksi intravena.

Haemoctin digunakan untuk pengobatan dan profilaksis perdarahan pada pasien dengan hemofilia A (kekurangan faktor VIII bawaan).

Produk ini dapat digunakan untuk mengobati kekurangan faktor VIII yang diderita.

Haemoctin tidak mengandung faktor von Willebrand dalam jumlah yang cukup secara farmakologis, sehingga tidak cocok untuk pengobatan penyakit von Willebrand.

2. Hal-hal perlu Anda ketahui sebelum menggunakan Haemoctin

Jangan gunakan Haemoctin,

- Apabila Anda alergi terhadap faktor koagulasi VIII atau salah satu bahan lain dari obat ini (tercantum di bagian 6). Reaksi alergi dapat berupa ruam, gatal, kesulitan bernapas, atau pembengkakan pada wajah, bibir, tenggorokan, atau lidah.

Peringatan dan pencegahan

Pembentukan inhibitor (antibodi) merupakan komplikasi yang diketahui dapat terjadi selama pengobatan yang menggunakan semua obat Faktor VIII. Inhibitor ini, terutama pada tingkat tinggi, mencegah pengobatan bekerja dengan baik, dan Anda atau anak Anda akan dipantau dengan seksama apakah mengalami perkembangan inhibitor ini. Jika Anda atau anak Anda mengalami pendarahan yang tidak terkendali akibat Haemoctin, segera beritahu dokter Anda.

Bila Anda memiliki faktor risiko kardiovaskular, terapi dengan Haemoctin dapat meningkatkan risiko kardiovaskular. Jika Anda merasa ragu, sebaiknya Anda membicarakan hal ini dengan dokter Anda.

Komplikasi terkait kateter: Jika alat akses vena sentral *(Central Venous Access Device (CVAD))* diperlukan, risiko komplikasi terkait CVAD termasuk infeksi lokal, bakteremia (adanya bakteri dalam aliran darah), dan trombosis (gumpalan darah di dalam pembuluh darah) lokasikateter harus dipertimbangkan.

Keamanan terhadap virus

Apabila obat dibuat dari darah atau plasma manusia, langkah-langkah tertentu dilakukan untuk mencegah infeksi menular ke pasien. Tindakan tersebut termasuk:

- memilih pendonor darah dan plasma secara hati-hati untuk memastikan tidak ada pendonor yang berisiko menularkan infeksi,

- menguji tanda-tanda virus/infeksi pada setiap donasi dan kumpulan plasma,
- melakukan langkah-langkah dalam pemrosesan darah atau plasma yang dapat menonaktifkan atau menghilangkan virus.

Terlepas dari langkah-langkah tersebut, apabila obat yang dibuat dari darah atau plasma manusia diberikan, kemungkinan penularan infeksi tidak dapat dihilangkan sepenuhnya. Ini juga berlaku untuk virus yang tidak dikenal atau virus baru atau jenis infeksi lainnya.

Langkah-langkah yang diambil dianggap efektif untuk virus berselubung seperti *human immunodeficiency virus* (HIV), virus hepatitis B dan virus hepatitis C, dan untuk virus hepatitis A tidak berselubung. Langkah-langkah yang diambil mungkin memiliki nilai terbatas terhadap virus yang tidak berselubung seperti parvovirus B19. Infeksi Parvovirus B19 bisa membahayakan wanita hamil (infeksi janin) dan bagi individu yang sistem kekebalannya menurun atau yang mengalami beberapa jenis anemia (misalnya penyakit sel sabit atau anemia hemolitik).

Dokter Anda mungkin menyarankan agar Anda mempertimbangkan vaksinasi terhadap hepatitis A dan B jika Anda secara teratur/berulang kali menerima produk Faktor VIII yang berasal dari plasma manusia.

Anda sebaiknya mencatat nama dan nomor batch obat setiap kali Anda menerima dosis Haemoctin untuk menyimpan catatan batch yang digunakan.

Anak-anak dan remaja

Peringatan dan tindakan pencegahan untuk penggunaan yang disebutkan untuk orang dewasa juga harus dipertimbangkan untuk anak-anak dan remaja.

Obat lain dan Haemoctin

Beri tahu dokter Anda jika Anda sedang menggunakan, baru saja menggunakan atau mungkin menggunakan obat lain.

Belum ada laporan mengenai interaksi antara Haemoctin dan produk obat lainnya.

Kehamilan, menyusui dan kesuburan

Jika Anda sedang hamil atau menyusui, menduga bahwa Anda mungkin hamil atau berencana untuk hamil, mintalah saran dari dokter Anda sebelum mengonsumsi obat ini.

Karena hemofilia A jarang terjadi pada wanita, belum ada kejadian tentang penggunaan faktor VIII selama kehamilan atau saat menyusui. Belum pernah dilakukan percobaan pada hewan selama kehamilan dan menyusui.

Berkendara dan menggunakan mesin

Haemoctin tidak memiliki atau memiliki pengaruh yang tidak signifikan terhadap kemampuan berkendara atau menggunakan mesin.

Haemoctin mengandung natrium

Haemoctin 250 mengandung hingga 16,1 mg (0,70 mmol) natrium (komponen utama garam masak/meja) di setiap vial. Ini setara dengan 0,81% dari asupan natrium harian maksimum yang direkomendasikan untuk orang dewasa.

Haemoctin 500/1000 mengandung hingga 32,2 mg (1,40 mmol) natrium (komponen utama dari garam masak/meja) di setiap vial. Ini setara dengan 1,61% dari asupan natrium harian maksimum yang direkomendasikan untuk orang dewasa.

3. Cara menggunakan Haemoctin

Haemoctin harus diberikan secara intravena (injeksi ke pembuluh darah). Pengobatan harus diawasi oleh dokter yang berpengalaman dalam pengobatan hemofilia A. Selalu gunakan Haemoctin persis seperti yang dikatakan dokter Anda. Anda harus memeriksakan diri ke dokter jika Anda merasa ragu.

Dosis dan durasi pengobatan tergantung pada tingkat keparahan kekurangan faktor VIII, lokasi dan tingkat perdarahan, dan kondisi klinis Anda. Dokter Anda akan menentukan dosis yang cocok untuk Anda.

Pastikan pekerjaan di semua langkah prosedur dilakukan dengan steril. ¶

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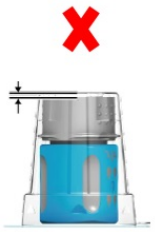
Gbr. 1a

Gbr. 1b



Gbr. 1c

Gbr. 2

Gbr. 3

Gbr. 4

Gbr. 5

Gbr. 6

Gbr. 7

Gbr. 8

Pelarutan konsentrat:

- Biarkan vial pelarut (air untuk injeksi) dan produk yang belum dibuka mencapai suhu ruangan. Jika menggunakan penangas air untuk pemanasan, pastikan air tidak mengenai penutup atau sumbat vial. Jika tidak, maka obat dapat terkontaminasi.
- **Sangat penting** untuk penggunaan sistem transfer yang tepat: sebelum membuka produk, pastikan bagian bawah sistem transfer yang berwarna putih berada tepat di dasar blister (Gbr. 1a: benar/ Gbr. 1b: salah). Jika tidak tepat: dorong sistem transfer ke bawah di dalam blister hingga bagian bawah sistem

transfer yang berwarna putih berada tepat di dasar blister (Gbr. 1c).

- Lepaskan penutup dari vial pelarut dan produk untuk membuka bagian tengah sumbat karet (Gbr. 2). Pastikan sumbat karet vial produk dan pelarut telah didisinfeksi.
- Lepaskan bagian atas kemasan sistem transfer (Gbr. 3).
- Letakkan botol pelarut di permukaan yang rata. Letakkan bagian biru dari sistem transfer di dalam blister tepat ke botol tegak yang berisi pelarut (Gbr. 4). Jangan memutar sistem transfer!
- Keluarkan bagian blister yang tersisa dari sistem transfer. Jangan memencet blister! Sekarang bagian putih dari sistem transfer terlihat (Gbr. 5).
- Letakkan vial produk di permukaan yang rata.
- Balikkan kombinasi sistem transfer dan vial pelarut. Dorong paku bagian putih adaptor lurus ke bawah melalui sumbat vial produk (Gbr. 6). Ruang hampa yang ada dalam botol produk menyebabkan pelarut mengalir ke dalam vial produk.
- Mengaduk botol produk pelan-pelan akan membantu melarutkan bubuk. Jangan mengocok kuat-kuat, semua busa harus dihindari! Larutannya bening atau sedikit buram.
- Setelah itu, buka bagian biru dari sistem transfer bersama dengan vial pelarut berlawanan arah jarum jam (Gbr. 7). Buang vial pelarut dengan bagian biru dari sistem transfer yang terpasang. Konektor Luer-Lock sekarang terlihat.

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Larutan yang siap digunakan harus segera digunakan setelah larut. Jangan gunakan larutan yang keruh atau mengandung partikel yang terlihat.

Injeksi:

- Setelah Anda melarutkan bubuk seperti dijelaskan di atas, pasangkan jarum suntik yang disertakan ke konektor Luer-Lock pada vial produk dengan bagian putih dari sistem transfer (Gbr. 8). Hal ini memungkinkan Anda untuk mudah menarik obat yang terlarut ke dalam jarum suntik. Filter terpisah tidak diperlukan karena sistem transfer memiliki filter integralnya sendiri.
- Lepaskan vial dengan hati-hati beserta bagian putih dari sistem transfer dari jarum suntik. Gunakan jarum kupu-kupu yang disertakan dan berikan segera melalui injeksi intravena lambat. Kecepatan injeksi tidak boleh melebihi 2-3 ml/menit.
- Setelah jarum kupu-kupu digunakan, jarum tersebut dapat diamankan dengan penutup pelindung.

Jika Anda menggunakan Haemoctin lebih dari yang seharusnya

Jika Anda yakin bahwa Anda telah menerima Haemoctin dalam jumlah yang berlebihan, beri tahu dokter Anda, yang akan memutuskan pengobatan lebih lanjut.

Jika Anda lupa menggunakan Haemoctin

Dalam hal ini dokter Anda akan memutuskan apakah diperlukan pengobatan lebih lanjut.

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Jika Anda berhenti menggunakan Haemoctin

Jangan berhenti menggunakan Haemoctin tanpa berkonsultasi dengan dokter Anda.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan produk ini, tanyakan kepada dokter atau apoteker Anda.

4. Kemungkinan efek samping

Seperti halnya semua obat, obat ini dapat menimbulkan efek samping, meski tidak semua orang mengalaminya.

Jika Anda mengalami salah satu dari efek berikut, segera beri tahu dokter Anda:

- kemerahan pada kulit
- rasa terbakar dan menyengat di tempat suntikan
- menggigil
- peronaan *(flushing)*
- sakit kepala
- gatal-gatal
- hipotensi
- lesu
- mual
- gelisah
- takikardia
- sesak dada
- kesemutan
- muntah
- mengi

Ini bisa merupakan alergi atau reaksi alergi serius (syok anafilaktik) atau reaksi hipersensitivitas.

Efek samping lain berikut telah diamati dengan Haemoctin yang Tidak diketahui: frekuensi tidak dapat diperkirakan dari data yang tersedia

- (anafilaksis) syok, reaksi alergi
- kemerahan pada kulit, gatal, ruam

Untuk anak-anak yang sebelumnya tidak diobati dengan obat Faktor VIII, antibodi inhibitor (lihat bagian 2) dapat terbentuk secara normal (lebih dari 1 dari 10 pasien); namun pasien yang sebelumnya telah diobati dengan Faktor VIII (lebih dari 150 hari pengobatan) risikonya jarang terjadi (kurang dari 1 dari 100 pasien). Jika risiko tersebut terjadi, obat yang Anda atau anak Anda konsumsi mungkin berhenti berfungsi dengan baik dan Anda atau anak Anda mungkin mengalami pendarahan terus-menerus. Jika ini terjadi, Anda harus segera menghubungi dokter Anda.

Efek samping pada anak-anak dan remaja

Kecuali pembentukan inhibitor (antibodi), efek samping pada anak diperkirakan sama dengan efek samping pada orang dewasa.

Pelaporan efek samping

Jika Anda mengalami efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam Brosur ini.

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5. Cara menyimpan Haemoctin

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Simpan vial di karton luar agar terhindar dari cahaya.

Jangan simpan pada suhu melebihi 25°C. Jangan dibekukan.

Jangan gunakan Haemoctin setelah tanggal kedaluwarsa yang tertera pada label vial dan karton.

Setelah kemasan pertama kali dibuka, produk harus segera digunakan. Larutan siap pakai harus segera digunakan setelah dilarutkan.

Setiap produk atau bahan limbah yang tidak terpakai harus dibuang sesuai dengan persyaratan setempat. Jangan buang obat melalui air limbah atau limbah rumah tangga. Tanyakan pada apoteker Anda mengenai cara membuang obat yang tidak diperlukan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Kandungan Haemoctin

- Zat aktifnya adalah Faktor koagulasi VIII yang berasal dari manusia
- Bahan lainnya adalah glisin, natrium klorida, natrium sitrat dan kalsium klorida.
- Vial pelarut berisi air untuk injeksi.

Bentuk Haemoctin dan isi kemasannya

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Serbuk putih dan pelarut bening tak berwarna untuk larutan untuk injeksi

Kemasan yang tersedia:

- **Dus, 1 vial serbuk (250 IU) + 1 vial air untuk injeksi (5 ml) + 1 disposable syringe + 1 transfer system dengan integral filter + 1 butterfly cannula. DKI1226000344A1**
- **Dus, 1 vial serbuk (500 IU) + 1 vial air untuk injeksi (10 ml) + 1 disposable syringe + 1 transfer system dengan integral filter + 1 butterfly cannula. DKI1226000344A1**
- **Dus, 1 vial serbuk (1000 IU) + 1 vial air untuk injeksi (10 ml) + 1 disposable syringe + 1 transfer system dengan integral filter + 1 butterfly cannula. DKI1226000344B1**

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.

Namun pada produk jadi tidak ditemukan adanya DNA babi.

Untuk pelaporan efek samping dan keluhan kualitas produk, dapat menghubungi:

Pusat Farmakovigilans PT Kimia Farma Tbk.

Email: pv@kimiafarma.co.id Tel: (021) 1500 255

Diproduksi Oleh:

Biotest AG

Landsteinerstrasse 5

63303 Dreieich

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EREG100303VR12500112

Dirilis oleh:

Biotest Pharma GmbH

Landsteinerstrasse 5

63303 Dreieich

Jerman

Telepon: +49 6103 801-0

Faks: +49 6103 801-150

Email: mail@biotest.com

Diimpor Oleh:

PT Kimia Farma Tbk.

Jl. Rawagelam V No. 1

Kawasan Industri Pulogadung

Jakarta, Indonesia 13930

Brosur ini terakhir direvisi pada 11/2025.

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