No. 0296- 03

PRAXBIND™*

Idarucizumab

Solution for Injection / Infusion

DESCRIPTION

Idarucizumab solution for injection/infusion 50 mg/mL is a clear to slightly opalescent, colorless to slightly yellow solution provided at a concentration of 50 mg/mL in a buffered, isotonic, preservative-free solution. The formulation is composed of 25 mM sodium acetate/acetate, 220 mM sorbitol and 0.2 g/L (0.02 w%) polysorbate 20 at pH 5.5. The container closure system consists of a Type 1 glass vial with a butyl rubber stopper, an aluminum cap and a label with integrated hanger.

COMPOSITION

1 vial of 50 ml contains idarucizumab	2.5 g

Excipient**:
Acetic acid glacial, polysorbate 20, sodium acetate trihydrate, sorbitol, water for injection

INDICATIONS / USAGE

Praxbind™ is a specific reversal agent for dabigatran and is indicated in patients treated with PRADAXA® (dabigatran etexilate) when rapid reversal of the anticoagulant effects of dabigatran is required:

- **For emergency surgery/urgent procedures**
- **In life-threatening or uncontrolled bleeding**

DOSAGE AND ADMINISTRATION

The recommended dose of Praxbind™ is 5 g. (2x2.5 g/50 ml).

Praxbind™ (2x2.5 g/50 ml) is administered intravenously, as two consecutive infusions over 5 to 10 minutes each or as a bolus injection.

In a limited number of patients, recurrence of plasma concentrations of unbound dabigatran and concomitant prolongation of clotting tests have occurred up to 24 hours after administration of idarucizumab (see section Pharmacological properties).

Administration of a second 5 g dose of Praxbind may be considered in the following situations:
• recurrence of clinically relevant bleeding together with prolonged clotting times, or
• patients require a second emergency surgery/urgent procedure and have prolonged clotting times.

Relevant coagulation parameters are activated Partial Thromboplastin Time (aPTT), diluted Thrombin Time (dTT) or Ecarin Clotting Time (ECT) (see section Pharmacological properties).

Patient with renal impairment
No dose adjustment is required in renally impaired patients. Renal impairment did not impact the reversal effect of idarucizumab (see section Use in Specific Population)

Paediatric Population
The safety and efficacy of Praxbind inchildren below the age of 18 years have not yet been established. No data are available (see section Use in Specific Population)

Restarting Antithrombotic Therapy
PRADAXA® (dabigatran etexilate) treatment can be re-initiated 24 hours after administration of Praxbind™, if the patient is clinically stable and adequate hemostasis has been achieved.

After administration of Praxbind™, other antithrombotic therapy (e.g. low- molecular weight heparin) can be started at any time, if the patient is clinically stable and adequate hemostasis has been achieved.

Absence of antithrombotic therapy exposes patients to the thrombotic risk of their underlying disease or condition.

INSTRUCTIONS FOR USE / HANDLING

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Praxbind™ must not be mixed with other medicinal products. A pre-existing intravenous line may be used for administration of Praxbind™. The line must be flushed with sterile sodium chloride 9 mg/ml (0.9 %) solution prior to and at the end of infusion. **No other infusion should be administered in parallel via the same intravenous access.**

Prior to use, the unopened vial may be kept at room temperature (up to 30°C) for up to 48 hours, if stored in the original package in order to protect from light. Once solution has been removed from the vial, chemical and physical in-use stability of idarucizumab has been demonstrated for 6 hours at room temperature. The solution should not be exposed to light for more than 6 hours.

Praxbind™ is for single-use only and does not contain preservatives.

No incompatibilities between Praxbind™ and polyvinyl chloride, polyethylene or polyurethane infusion sets or polypropylene syringes have been observed.

CONTRAINDICATIONS
None.

SPECIAL WARNINGS AND PRECAUTIONS

Idarucizumab binds specifically to dabigatran and reverses its anticoagulant effect. It will not reverse the effects of other anticoagulant (see Pharmacodynamics).

Praxbind™ treatment can be used in conjunction with standard supportive measures, which should be considered as medically appropriate.

Hypersensitivity

The risk of using Praxbind™ in patients with known hypersensitivity (e.g. anaphylactoid reaction) to idarucizumab or to any of the excipients needs to be weighed cautiously against the potential benefit of such an emergency treatment. If an anaphylactic reaction or other serious allergic reaction occurs, administration of Praxbind™ should be discontinued immediately and appropriate therapy initiated.

Hereditary fructose intolerance

The recommended dose of Praxbind™ contains 4 g sorbitol as an excipient. In patients with hereditary fructose intolerance, parenteral administration of sorbitol has been associated with reports of hypoglycemia, hypophosphatemia, metabolic acidosis, increase in uric acid, acute liver failure with breakdown of excretory and synthetic function, and death. Therefore, in patients with hereditary fructose intolerance the risk of treatment with Praxbind™ must be weighed against the potential benefit of such an emergency treatment.

Thromboembolic Events
Patients being treated with dabigatran have underlying disease states that predispose them to thromboembolic events. Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. To reduce this risk, resumption of anticoagulant therapy should be considered as soon as medically appropriate (see section Dosage and administration).

Sodium content
This medicinal product contains 2,2 mmol (or 50 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

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

USE IN SPECIFIC POPULATIONS

Fertility, Pregnancy and Lactation

Pregnancy

There are no data for the use of Praxbind™ in pregnant women. Reproductive and developmental toxicity studies have not been performed, given the nature and the intended clinical use of the medicinal product. **Praxbind™ may be used during pregnancy, if the expected clinical benefit outweighs the potential risks.**

Lactation

It is unknown whether idarucizumab is excreted in human milk.

Fertility

There are no data on the effect of Praxbind™ on fertility.

Renal impairment

In Phase I studies Praxbind™ has been investigated in subjects with a creatinine clearance ranging from 44 to 213 mL/min. Subjects with a creatinine clearance below 44 mL/min have not been studied in Phase I.

Depending on the degree of renal impairment the total clearance was reduced compared to healthy subjects, leading to an increased exposure of idarucizumab.

Based on pharmacokinetic data from 347 patients with different degrees of renal function (median creatinine clearance 21-99 mL/min) it is estimated that mean idarucizumab exposure (AUC_{0-24h}) increases by 38% in patients with mild (CrCl 50-<80 mL/min), by 90% in moderate (30-<50 mL/min) and by 146% in severe (0-<30 mL/min) renal impairment. Since dabigatran is also excreted primarily via the kidneys, increases in the exposure to dabigatran are also seen with worsening renal function.

Based on these data and the extent of reversal of the anticoagulant effect of dabigatran in patients, renal impairment does not impact the reversal effect of idarucizumab.

Hepatic impairment

An impact of hepatic impairment, assessed by hepatic injury as determined by elevated liver function tests, on the pharmacokinetics of idarucizumab has not been observed. No dose adjustment is required in patients with hepatic injury.

Idarucizumab has been studied in 58 patients with varying degrees of hepatic impairment. Compared to 272 patients without hepatic impairment, the median AUC of idarucizumab was changed by -6%, 37% and 10% in patients with AST/ALT elevations of 1 to <2x ULN (N=34), 2 to <3x ULN (N=3) and >3x ULN (N=21), respectively. Based on pharmacokinetic data from 12 patients with liver disease, the AUC of idarucizumab was increased by 10% as compared to patients without liver disease.

Geriatric patients/Sex/Race

Based on population pharmacokinetic analyses, sex, age, and race do not have a clinically meaningful effect on the pharmacokinetics of idarucizumab.

Paediatric patients

The safety and efficacy of Praxbind™ in the paediatric population has not been established.

INTERACTIONS

No formal interaction studies with Praxbind™ and other medicinal products have been performed. Based on the pharmacokinetic properties and the high specificity in binding to dabigatran, clinically relevant interactions with other medicinal products are considered unlikely.
Preclinical investigations have shown no interactions with volume expanders,

coagulation factor concentrates and anticoagulants other than dabigatran (see Pharmacodynamics)

SIDE EFFECTS

In a phase III trial the safety of PraxbindTM has been evaluated in 503 patients, who had uncontrolled bleeding or required emergency surgery or procedures and were under treatment with PRADAXA, as well as in 224 volunteers in phase I trials.

No adverse reactions have been identified.

OVERDOSE

There is no clinical experience with overdoses of Praxbind™.

The highest dose of Praxbind™ studied in healthy subjects was 8 g. No safety signals have been identified in this group.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: all other therapeutic products, antidotes
ATC code: V03AB37

Mode of Action

Idarucizumab is a specific reversal agent for dabigatran. It is a humanized monoclonal antibody fragment (Fab) that binds to dabigatran with very high affinity, approximately 300- fold more potent than the binding affinity of dabigatran for thrombin. The idarucizumab- dabigatran complex is characterised by a rapid on-rate and extremely slow off-rate resulting in a very stable complex. Idarucizumab potently and specifically binds to dabigatran and its metabolites and neutralises their anticoagulant effect.

Clinical Trials

Three randomised, double-blind, placebo-controlled Phase I studies in 283 subjects (224 treated with idarucizumab) were conducted to assess the safety, efficacy, tolerability, pharmacokinetics and pharmacodynamics of idarucizumab, given alone or after administration of dabigatran etexilate. The investigated population consisted of healthy subjects and subjects exhibiting specific population characteristics covering age, body weight, race, sex and renal impairment. In these studies the doses of idarucizumab ranged from 20 mg to 8 g and the infusion times ranged from 5 minutes to 1 hour.

Representative values for pharmacokinetic and pharmacodynamics parameters were established on the basis of healthy subjects aged 45-64 years receiving 5 g idarucizumab (see Pharmacokinetics and Pharmacodynamics).

One prospective, open-label, non-randomized, uncontrolled study (RE-VERSE AD) was conducted to investigate the treatment of adult patients who presented with dabigatran-related life-threatening or uncontrolled bleeding (Group A) or who required emergency surgery or urgent procedures (Group B). The primary endpoint was the maximum percentage reversal of the anticoagulant effect of dabigatran within 4 hours after the administration of idarucizumab, based on central laboratory determination of dilute thrombin time (dTT) or ecarin clotting time (ECT). A key secondary endpoint was the restoration of haemostasis.

RE-VERSE AD included data for 503 patients: 301 patients with serious bleeding (Group A) and 202 patients requiring an urgent procedure/surgery (Group B). Approximately half of the patients in each group were male. The median age was 78 years and the median creatinine clearance was 52.6 mL/min. 61.5% of patients in Group A and 62.4% of patients in Group B had been treated with dabigatran 110 mg twice daily.

Reversal was only evaluable for those patients showing prolonged coagulation times prior to idarucizumab treatment. Most patients, in both Groups A and B, achieved complete reversal of the anticoagulant effect of dabigatran (dTT: 98.7%; ECT: 82.2%; aPTT: 92.5% of evaluable patients, respectively) in the first 4 hours after administration of 5 g idarucizumab. Reversal effects were evident immediately after administration.

Figure 1 – Reversal of dabigatran-induced clotting time prolongation determined by dTT in 90 patients from the RE-VERSE AD study (N=487)

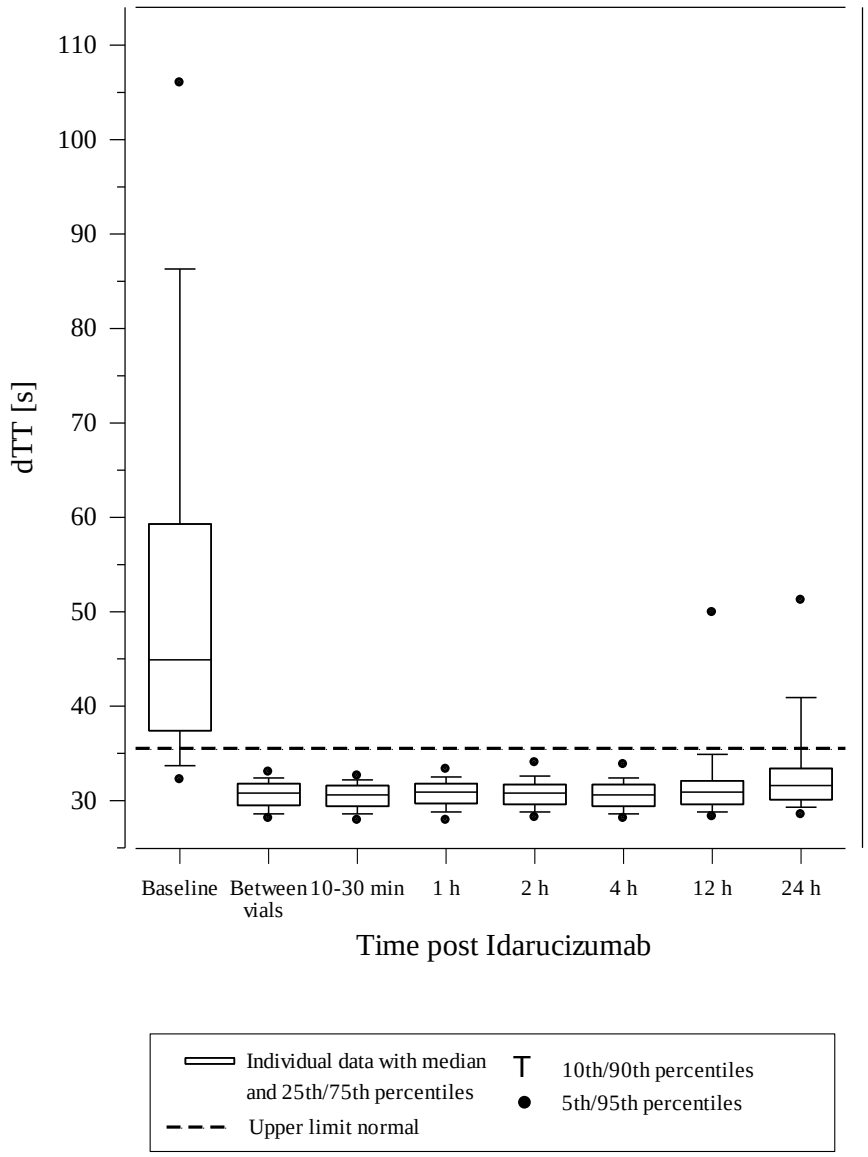

110
100
90
80
70
60
50
40
30
dTT [s]
Baseline
Between vials
10-30 min
1 h
2 h
4 h
12 h
24 h
Time post Idarucizumab
Individual data with median and 25th/75th percentiles
Upper limit normal
10th/90th percentiles
5th/95th percentiles

Figure 2 – Reversal of dabigatran-induced clotting time prolongation determined by ECT in patients from the RE-VERSE AD study (N=487)

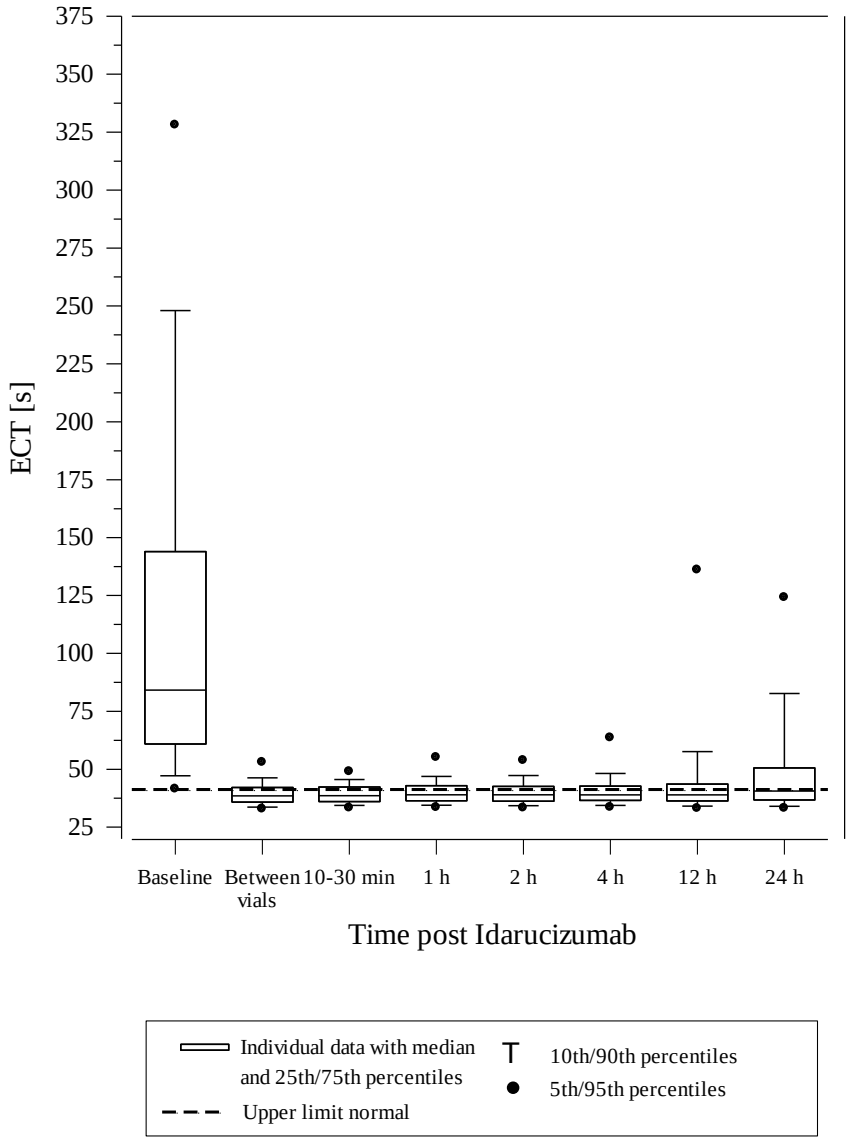
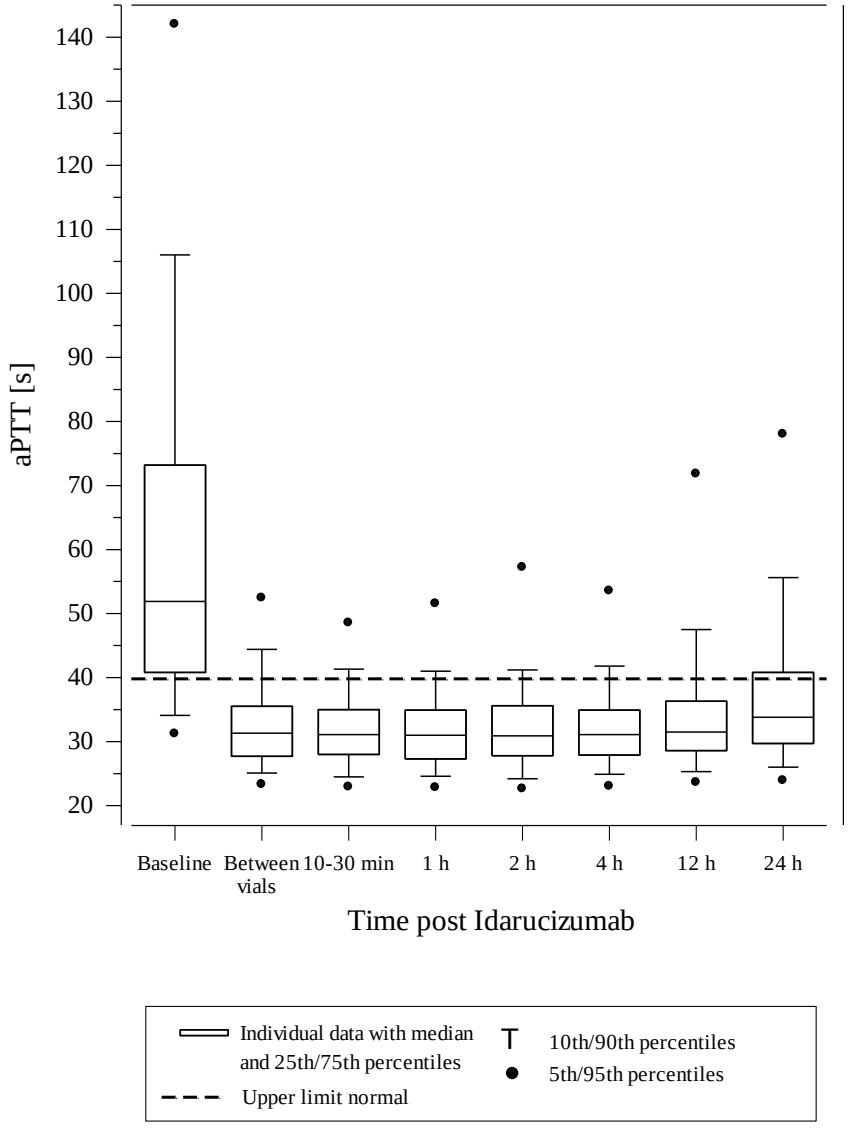


Figure 3 – Reversal of dabigatran-induced clotting time prolongation determined by aPTT in 486 patients from the RE-VERSE AD study



Restoration of haemostasis was achieved in 80.3% of evaluable patients who had serious bleeding and normal haemostasis was observed in 93.4% of patients who required an urgent procedure.

Of the total 503 patients, 101 patients died; each of these deaths could be attributed either as a complication of the index event or associated with co-morbidities. Thrombotic events were reported in 34 patients, (23 out of the 34 patients were not on antithrombotic therapy at the time of the event), and in each of these cases, the thrombotic event could be attributed to the underlying medical condition of the patient. Mild symptoms of potential hypersensitivity (pyrexia, bronchospasm, hyperventilation, rash or pruritus) were reported. A causal relationship to idarucizumab could not be established.

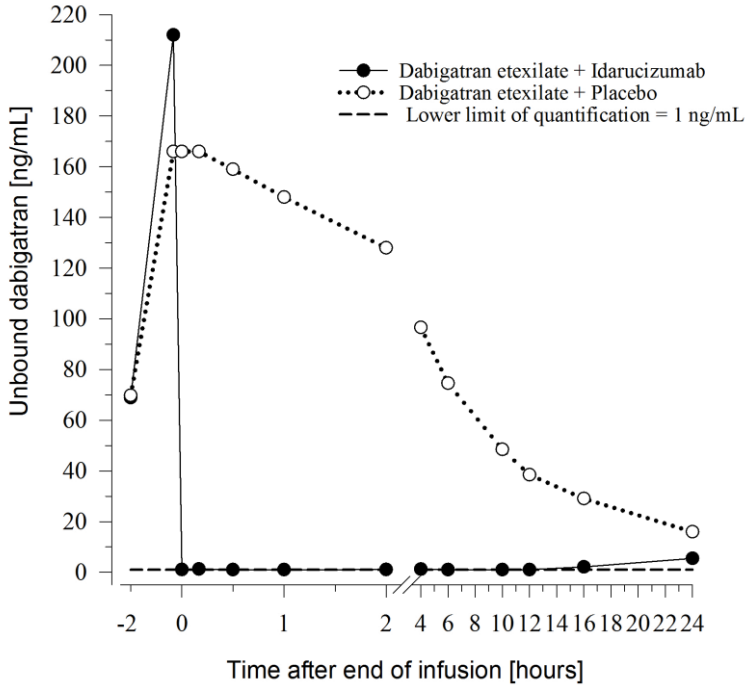
Pharmacodynamics

The pharmacodynamics of idarucizumab after administration of dabigatran etexilate were investigated in healthy subjects aged 45 to 64 years receiving a dose of 5 g as intravenous infusion. The median peak dabigatran exposure in the investigated healthy subjects was in the range of a twice daily administration of 150 mg dabigatran etexilate in patients.

Effect of idarucizumab on the exposure and anticoagulant activity of dabigatran
Immediately after the administration of idarucizumab, the plasma concentrations of unbound dabigatran were reduced by more than 99%, resulting in levels with no anticoagulant activity.

The majority of the patients showed sustained reversal of dabigatran plasma concentrations up to 12 hours (≥90%). In a subset of patients, recurrence of plasma levels of unbound dabigatran and concomitant elevation of clotting tests was observed, possibly due to re-distribution of dabigatran from the periphery. This occurred 1-24 hours after administration of idarucizumab mainly at timepoints ≥12 hours.

Figure 4 – Plasma-levels of unbound dabigatran in the representative group of healthy subjects (administration of idarucizumab or placebo at 0 h)



Dabigatran prolongs the clotting time of coagulation markers such as diluted Thrombin Time (dTT), Thrombin Time (TT), activated Partial Thromboplastin Time (aPTT) and Ecarin Clotting Time (ECT), which provide an approximate indication of the anticoagulation intensity. A value in the normal range after administration of idarucizumab indicates that a patient is no longer anticoagulated. A value above the normal range may reflect residual active dabigatran or other clinical conditions e.g., presence of other drugs or transfusion coagulopathy. These tests were used to assess the anticoagulant effect of dabigatran. A complete and sustained reversal of dabigatran-induced clotting time prolongation was observed immediately after the idarucizumab infusion, **lasting** over the entire observation period of at least 24 h.

Figure 5 – Reversal of dabigatran-induced clotting time prolongation determined by dTT in the representative group of healthy subjects (administration of idarucizumab or placebo at 0 h)

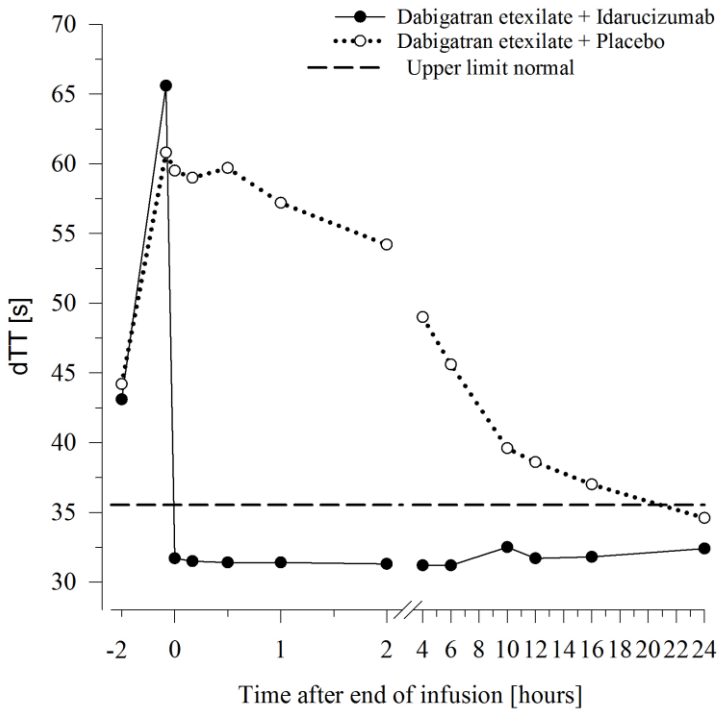
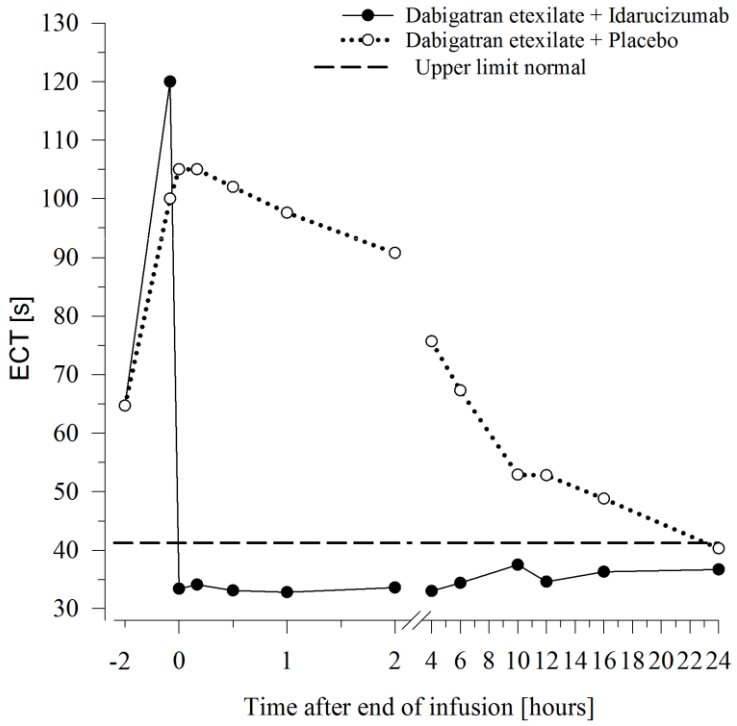


Figure 6 – Reversal of dabigatran-induced clotting time prolongation determined by ECT in the representative group of healthy subjects (administration of idarucizumab or placebo at 0 h)


Dabigatran etexilate + Idarucizumab
Dabigatran etexilate + Placebo
Upper limit normal
ECT [s]
130
120
110
100
90
80
70
60
50
40
30
-2
0
1
2
4
6
8
10
12
14
16
18
20
22
24
Time after end of infusion [hours]

Thrombin generation parameters

Dabigatran exerts pronounced effects on parameters of the endogenous thrombin potential (ETP). Idarucizumab treatment normalised both thrombin lag time ratio and time to peak ratio to baseline levels as determined 0.5 to 12 hours after the end of the idarucizumab infusion. Idarucizumab alone has shown no procoagulant effect measured as ETP. This suggests that idarucizumab has no prothrombotic effect.

Re-administration of dabigatran etexilate

24 hours after the idarucizumab infusion, re-administration of dabigatran etexilate resulted in expected anticoagulant activity.

Immunogenicity

Serum samples from 283 subjects in phase I trials (224 volunteers treated with idarucizumab) and 501 patients were tested for antibodies to idarucizumab before and after treatment.

Pre-existing antibodies with cross-reactivity to idarucizumab were detected in approximately 13 % (36/283) of the phase I subjects and 3.8% (19/501) of the patients. No impact on the pharmacokinetics or the reversal effect of idarucizumab or hypersensitivity reactions were observed.

Treatment-emergent possibly persistent anti-idarucizumab antibodies with low titers were observed in 4 % (10/224) of the phase I subjects and 1.6% (8/501) of the patients suggesting a low immunogenic potential of idarucizumab. In a subgroup of 6 phase I subjects, idarucizumab was administered a second time, two months after the first administration. No anti-idarucizumab antibodies were detected in these subjects prior to the second administration. In one subject, treatment-emergent anti-idarucizumab antibodies were detected after the second administration. Nine patients were re-dosed with idarucizumab. All nine patients were re-dosed within 6 days after the first idarucizumab dose. None of the patients re-dosed with idarucizumab tested positive for anti-idarucizumab antibodies.

Preclinical pharmacodynamics

A trauma model in pigs was performed using a blunt liver injury after dosing with dabigatran to achieve supratherapeutic concentrations of about 10-fold of human plasma levels. Idarucizumab effectively and rapidly reversed the life-threatening bleeding within 15 min after the injection. All pigs survived at idarucizumab doses of approximately 2.5 and 5 g. Without idarucizumab, the mortality in the anticoagulated group was 100%.

Preclinical investigations with idarucizumab have shown no interactions with

- volume expanders.
- coagulation factor concentrates, such as prothrombin complex concentrates

(PCCs, e.g. 3 factor and 4 factor), activated PCCs (aPCCs) and recombinant factor VIIa.

- other anticoagulants (e.g. thrombin inhibitors other than dabigatran, Factor Xa inhibitors including low-molecular weight heparin, vitamin K-antagonists, heparin). Thus idarucizumab will not reverse the effects of other anticoagulants.

Pharmacokinetics

The pharmacokinetics of idarucizumab were investigated in healthy subjects aged 45 to 64 years receiving a dose of 5 g as intravenous infusion.

Distribution

Idarucizumab exhibited multiphasic disposition kinetics and limited extravascular distribution. Following the intravenous infusion of a 5 g dose, the geometric mean volume of distribution at steady state (V_{SS}) was 8.9 L (geometric coefficient of variation (gCV) 24.8%). In the terminal phase, the volume of distribution (V_Z) was 41.8 L (gCV 22.3%).

Biotransformation

Several pathways have been described that may contribute to the metabolism of antibodies. All of these pathways involve biodegradation of the antibody to smaller molecules, i.e. small peptides or amino acids which are then reabsorbed and incorporated in the general protein synthesis.

Elimination

Idarucizumab was rapidly eliminated with a total clearance of 47.0 mL/min (gCV 18.4%), an initial half-life of 47 minutes (gCV 11.4%) and a terminal half-life of 10.3 h (gCV 18.9%). After intravenous administration of 5 g idarucizumab, 32.1% (gCV 60.0%) of the dose was recovered in urine within a collection period of 6 hours and less than 1% in the following 18 hours. The remaining part of the dose is assumed to be eliminated via protein catabolism, mainly in the kidney.

After treatment with idarucizumab proteinuria has been observed. The transient proteinuria is a physiologic reaction to renal protein overflow after bolus/short term application of 5 g idarucizumab intravenously. The transient proteinuria usually peaked about 4 h after idarucizumab administration and normalised within 12-24 hours. In single cases the transient proteinuria persisted for more than 24 hours. The transient proteinuria is not indicative of renal damage, which should be taken into account for urine testing.

TOXICOLOGY

Preclinical data reveal no special hazard for humans based on repeated dose toxicity studies of up to four weeks in rats and two weeks in monkeys. Safety pharmacology studies have demonstrated no effects on the respiratory, central nervous or cardiovascular system.

Studies to evaluate the mutagenic and carcinogenic potential of idarucizumab have not been performed. Based on its mechanism of action and the characteristics of proteins no carcinogenic or genotoxic effects are anticipated.

Studies to assess the potential reproductive effects of idarucizumab have not been performed. No treatment-related effects have been identified in reproductive tissues of either sex during repeat dose intravenous toxicity studies of up to four weeks in the rat and two weeks in monkeys. Additionally, no idarucizumab binding to human reproductive tissues was observed in a tissue cross-reactivity study. Therefore, preclinical results do not suggest a risk to fertility or embryo-fetal development.

No local irritation of the blood vessel was observed after i.v. or paravenous administration of idarucizumab. The idarucizumab formulation did not produce hemolysis of human whole blood in vitro.

Storage Conditions

Store in a refrigerator, 2-8°C
Do not freeze
Keep the container in the outer carton in order to protect from light.
Store in a safe place out of the reach of children!

Availability

Vial PRAXBIND 50 mg/ml
Box, 2 vials @ 50 ml No. Reg.

On medical prescription only
Harus dengan resep dokter

Manufactured by:
Boehringer Ingelheim Pharma GmbH & Co.KG,
Biberach, Germany

For:
Boehringer Ingelheim International GmbH,
Ingelheim am Rhein, Germany

Imported by:
PT. Tunggal Idaman Abdi Jakarta, Indonesia

Lembar Informasi Obat: Informasi untuk pasien dan pengguna obat

Praxbind 50 mg/mL

Idarucizumab

Larutan untuk injeksi / infus

Obat ini merupakan obat dalam pengawasan khusus. Hal ini untuk membantu didapatkannya informasi baru keamanan obat secara cepat. Anda dapat membantu dengan melaporkan efek samping apapun yang terjadi. Lihat akhir bab ini tentang bagaimana cara melaporkan efek samping.

Bacalah seluruh lembar informasi ini dengan seksama sebelum mulai mengonsumsi obat ini karena lembar ini berisi informasi yang bermanfaat untuk anda. Harap dicatat bahwa obat ini sebagian besar digunakan dalam situasi kegawatan dan dokter harus memutuskan bilakah anda membutuhkannya.

- Simpanlah lembar informasi ini. Anda mungkin akan perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakanlah pada dokter atau perawat Anda.
- Jika Anda mengalami efek samping, konsultasikan dengan dokter atau perawat Anda, termasuk jika efek samping yang dialami belum ada dalam daftar pada lembar ini. Lihat bab 4.

Apa yang ada pada lembar ini

1. Apakah Praxbind dan indikasi pemberiannya

Pemerian Praxbind

Praxbind larutan untuk injeksi / infus 50 mg/mL adalah larutan bening hingga agak kekuningan, tidak berwarna hingga sedikit kuning, tersedia dalam konsentrasi 50mg/mL dalam larutan buffer, isotonik, bebas dari pengawet. Formulasi terdiri dari 25 mM sodium asetat/asetat, 220 mM sorbitol dan 0.2 g/L (0.02 w%) polisorbat 20 pada pH 5.5. Sistem kemasan terdiri dari vial kaca tipe 1, penutup karet butil, tutup alumunium dan label dengan gantungan terintegrasi.

Apakah Praxbind

Praxbind mengandung bahan aktif idarucizumab dan merupakan zat pembalik spesifik untuk dabigatran (Pradaxa), obat pengencer darah yang menghambat substansi dalam tubuh yang berkaitan dengan pembentukan bekuan darah. Praxbind digunakan untuk memerangkap dabigatran secara cepat yang bertujuan untuk menginaktivasi efeknya.

Digunakan untuk apakah Praxbind

Praxbind digunakan dalam situasi kegawatan ketika dokter anda memutuskan bahwa saat tersebut dibutuhkan inaktivasi cepat efek Pradaxa

- Untuk prosedur pembedahan/kegawatan
- Perdarahan mengancam jiwa atau tidak terkendali

2. Apa yang perlu Anda ketahui ketika anda menerima Praxbind

Peringatan dan perhatian

Beritahukan kepada dokter atau perawat anda

- bila anda alergi terhadap idarucizumab atau zat lainnya yang terdapat dalam bab 6
- bila anda memiliki penyakit genetik yang disebut intoleransi fruktosa herediter. Pada kasus ini zat sorbitol yang terkandung dalam obat ini dapat menyebabkan reaksi tidak diinginkan yang serius

Mereka akan mempertimbangkan hal tersebut diatas sebelum memberikan Praxbind kepada anda.

Obat ini hanya akan mengeluarkan dabigatran dari tubuh anda. Obat ini tidak mengeluarkan obat lainnya yang digunakan untuk mencegah pembentukan bekuan darah.

Anak

Tidak terdapat informasi mengenai penggunaan Praxbind pada anak.

Pemakaian obat lain dan Praxbind

Beritahukan kepada dokter anda bila anda sedang, baru saja, atau mungkin mengonsumsi obat lainnya.

Obat ini didesain untuk hanya mengikat dabigatran. Oleh karena itu sangat kecil kemungkinan obat lain akan memengaruhi efek Praxbind atau Praxbind akan memengaruhi efek obat lainnya .

Kehamilan dan menyusui

Beritahukan kepada dokter anda bila anda hamil atau menyusui, berpikir anda mungkin hamil atau merencanakan untuk hamil.

Tidak terdapat informasi mengenai efek obat ini pada perempuan hamil atau menyusui. Praxbind tidak memengaruhi tubuh, sehingga dokter anda dapat memutuskan untuk memberikan obat ini kepada anda dengan mempertimbangkan risiko potensial.

3. Bagaimana cara menggunakan Praxbind

Dosis yang direkomendasikan adalah 5 g (2 vial @ 50 mL).

Dokter atau perawat anda akan memberikan obat ini kepada anda melalui injeksi atau infus kedalam pembuluh darah vena.

Setelah anda menerima Praxbind, dokter anda akan memutuskan mengenai kelanjutan pengobatan anda untuk mencegah pembentukan bekuan darah. Pradaxa dapat diberikan lagi setelah 24 jam.

Informasi lebih rinci untuk dokter atau perawat anda mengenai bagaimana cara memberikan Praxbind dapat anda temukan di akhir lembar informasi ini (lihat 'Instruksi Cara Penggunaan).

Bila anda memiliki pertanyaan lebih lanjut mengenai cara menggunakan obat ini, bertanyalah kepada dokter anda.

4. Efek samping yang mungkin terjadi

Seperti semua obat lainnya, obat ini dapat menyebabkan efek samping, meskipun tidak semua orang mengalaminya.

Obat ini masih dalam uji klinis. Hingga saat ini, belum teridentifikasi efek samping.

Melaporkan efek samping

Bila anda mengalami efek samping apapun, bicaralah kepada dokter atau perawat anda. Anda dapat juga melaporkan efek samping yang terjadi secara lngsung melalui sistem pelaporan nasional. Dengan melaporkan efek samping maka anda dapat membantu memberikan lebih banyak informasi mengenai keamanan obat ini.

5. Bagaimana cara menyimpan Praxbind

Simpanlah obat ini jauh dari penglihatan dan jangkauan anak-anak.

Jangan menggunakan obat ini setelah tanggal kadaluarsa yang tertulis pada vial dan karton setelah 'EXP'. Tanggal kadaluarsa merujuk pada hari terakhir pada bulan tersebut.

Simpan obat ini dalam lemari pendingin (2-8°C).

Jangan dibekukan.

Simpan obat dalam paket aslinya untuk melindunginya dari cahaya.

Pada saat dibuka, Praxbind harus segera digunakan.

6. Isi kemasan dan informasi lainnya

Apakah yang terkandung dalam Praxbind

- Zat aktif idarucizumab.
- Bahan lainnya adalah natrium trihidrat asetat, asam asetat, sorbitol, polisorbat 20 dan air untuk injeksi.

Seperti apakah tampilan Praxbind dan apakah isi kemasannya

Larutan Praxbind untuk injeksi/infus adalah larutan bening hingga sedikit opalesen, tanpa warna hingga sedikit kekuningan yang terdapat dalam vial gelas dengan penyumbat karet butil dan penutup aluminium.

Kemasan

Vial PRAXBIND 50 mg/ml

Dus, 2 vial @ 50 ml No. Reg.

Harus dengan resep dokter.

Diproduksi oleh :

Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach, Jerman

Untuk :

Boehringer Ingelheim International GmbH, Jerman

Diimport oleh :

PT. Tunggal Idaman Abdi Jakarta, Indonesia

Informasi berikut ini ditujukan hanya untuk profesional kesehatan:

Praxbind secara spesifik mengikat dabigatran dan membalik efek antikoagulannya. Obat ini tidak akan membalik efek antikoagulan lainnya.

Pengobatan Praxbind dapat digunakan bersama dengan langkah-langkah dukungan standar, yang harus dipertimbangkan sesuai medis.

Dosis Praxbind yang direkomendasikan mengandung sorbitol 4 g sebagai eksipien. Pada pasien dengan intoleransi fruktosa herediter terdapat risiko terjadi reaksi tidak diinginkan serius, yang sebaiknya dipertimbangkan terhadap manfaat pengobatan darurat dengan Praxbind.

Dosis dan cara pemberian :

Dosis Praxbind yang direkomendasikan adalah 5 g. Dua vial 50 ml (2x2,5 g) merupakan satu dosis lengkap.

Dosis lengkap 5 g diberikan secara intravena, sebagai dua infus berkesinambungan masing-masing selama 5 hingga 10 menit atau injeksi bolus.

Pengobatan Pradaxa dapat diinisiasi kembali 24 jam setelah pemberian Praxbind, bila pasien secara klinis stabil dan hemostasis yang adekuat dapat dicapai.

Setelah pemberian Praxbind, terapi antitrombotik lainnya (contohnya heparin berat molekuler rendah) dapat dimulaai kapan saja, bila pasien secara klinis stabil dan hemostasis yang adekuat telah dicapai.

Tidak digunakannya terapi antitrombotik akan memajankan pasien kepada risiko trombotik akibat penyakit atau kondisi dasar mereka.

Instruksi Cara Penggunaan:

Praxbind tidak boleh dicampur dengan produk obat lainnya. Jalur intravena yang telah ada dapat digunakan untuk Praxbind. Jalur ini sebaiknya dialirkan dengan larutan natrium klorida (NaCl) 9 mg/ml (0.9%) untuk injeksi sebelum dan setelah infus. Jangan berikan infus lain secara paralel melalui akses intravena yang sama.

Praxbind hanya diberikan dosis tunggal dan tidak mengandung bahan pengawet.

Sebelum digunakan, vial yang belum dibuka dapat disimpan pada suhu ruang (25°C) hingga 48 jam, bila disimpan dalam paket aslinya agar terlindung dari cahaya, atau hingga 6 jam bila terpajan oleh sinar. Stabilitas kimia dan fisis idarucizumab ketika digunakan dapat terjaga selama 1 jam pada suhu ruang.

Dari sudut pandang mikrobiologis, kecuali metode cara membuka menghindari risiko kontaminasi mikrobial, obat ini sebaiknya digunakan segera setelah dibuka. Bila tidak segera digunakan maka waktu simpan dan kondisi sebelum digunakan merupakan tanggung jawab pengguna.

Tidak terdapat inkompatibilitas antara Praxbind dan set infus polivinil klorida, polietilen atau poliuretan atau siring polipropilen.