

**VENOFER
IRON SUCROSE COMPLEX
INJECTION**

Composition

Each 5 mL ampoule contains 20 mg/mL Iron as Iron Sucrose corresponding to 100 mg Iron per ampoule.

List of excipients

Excipients:

Water for injection

Sodium hydroxide (for pH adjustment)

Product description

Venofer is supplied as a dark brown, non transparent, aqueous, solution with a pH of 10.5-11.0 and an osmolarity of 1,150-1,350 mOsmol/L.

Mode of action

Pharmacological Properties

Pharmacodynamic Properties

The ferrokinetics of Venofer labelled with ^{59}Fe and ^{52}Fe were assessed in 5 patients with anaemia and chronic renal failure. Plasma clearance of ^{52}Fe was in the range of 60 to 100 minutes. ^{52}Fe was distributed to the liver, spleen and bone marrow. At two weeks after administration, the maximum red blood cell utilisation of ^{59}Fe ranged from 62% to 97%.

Pharmacokinetic Properties

Following intravenous injection of a single dose of Venofer containing 100 mg Fe (III) in healthy volunteers, maximum iron levels, averaging 538 $\mu\text{mol/L}$, were obtained 10 minutes after injection. The volume of distribution of the central compartment corresponded well to the volume plasma (approx. 3 Litres).

The iron injected was rapidly cleared from the plasma, the terminal half-life being approx. 6 h. The volume of distribution at steady state was about 8 Litres, indicating a low iron distribution in the body fluid. Due to the lower stability of iron sucrose in comparison to transferrin, a competitive exchange of iron to transferrin was observed. This resulted in iron transport of approx. 31 mg Fe (III) / 24 h.

Renal elimination of iron, occurring in the first 4 h after injection, corresponds to less than 5% of the total body clearance. After 24 h the plasma levels of iron were reduced to the pre-dose iron level and about 75% of the dosage of sucrose was excreted.

Preclinical Safety Data

There are no preclinical data of relevance to the prescriber that are additional to information already in other sections of the SPC.

Indications

Adult

Venofer is indicated for the treatment of iron deficiency in adult patients in the following indications:

- Where there is a clinical need for a rapid iron supply,
- In patients who cannot tolerate oral iron therapy or who are non-compliant,
- Where oral iron preparations are ineffective

Venofer should only be administered where the indication is confirmed by appropriate investigations (in adult patients with Haemoglobin 7 - ≤ 13 g/dL and hematocrit $< 39\%$ (man) or Hb 7 - < 12 g/dL and hematocrit $< 36\%$ (Non-pregnant women) and serum ferritin < 15 $\mu\text{g/L}$ (man or women with depleted iron stores or adult patients who have CKD with TSAT $< 25\%$).

Pediatric

Venofer is indicated for iron maintenance treatment in Pediatric Patients (2 years of age and older) with Haemodialysis Dependent-Chronic Kidney Disease.

Contraindications

The use of Venofer is contraindicated in cases of:

- known hypersensitivity to Venofer or any of its excipients
- anaemias not attributable to iron deficiency
- iron overload or disturbances in utilization of iron
- patients with a history of asthma, eczema or other atopic allergy, because they are more susceptible to experience allergic reactions
- pregnancy first trimester
- history of cirrhosis or hepatitis or the presence of serum transaminase at three times the upper limit
- acute or chronic infection, because parenteral iron administration may exacerbate a bacterial or viral infection

Undesirable Effects

Very rarely anaphylactic like reactions may occur. These may be potentially fatal.

Occasionally the following undesirable effects have been reported with a frequency $\geq$ one percent: metallic taste, headache, nausea, vomiting, hypotension, hypertension, and injection/infusion site reaction.

Less frequently paraesthesia, abdominal disorders, muscular pain, fever, urticaria, flushing, oedema of the extremities, dyspnoea, anaphylactoid (pseudoallergic) reactions, dizziness, pruritus, rash, asthenia, fatigue, syncope, somnolence, palpitations, chromaturia, chest pain, hyperhidrosis, and pyrexia have been reported. In the region of the punctured vein, phlebitis and venous spasm have been observed.

Undesirable effects under investigations including alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, serum ferritin increased, and blood lactate dehydrogenase increased.

Side effect reporting contact

If any adverse events or side effects related to the use of this medicine, consult a doctor, pharmacist, or nurse. You can also report adverse events or side effects to PT Combiphar by contacting Combi Care Center via hotline 0800-1-800088 or WhatsApp at 0818 06800088 or email combicarecenter@combiphar.com and/or to the BPOM Pharmacovigilance Center via email pv-center@pom.go.id.

Special Warnings and Precautions for Use

Parenterally administered iron preparations can cause severe allergic or anaphylactoid reactions. Which may be potentially fatal. Therefore, facilities for cardio-pulmonary resuscitation must be available.

In the event of a serious anaphylactic or allergic reaction, administration of Venofer must be stopped, intramuscular adrenaline should be administered immediately and other supportive measures initiated in line with the established cardio-pulmonary resuscitation procedures of the clinic or hospital.

Mild allergic reactions should be managed by stopping the administration of Venofer and administering antihistamines. Hypotensive episodes may occur if the injection is administered too rapidly. Patients with low iron binding capacity and/or folic acid deficiency are particularly at risk of an allergic or anaphylactoid reaction. In cases of inadvertent paravenous leakage, and if the needle is still inserted, rinse with a small amount of 0.9% sodium chloride solution.

There is also an increased risk of hypersensitivity reactions to parenteral iron complexes in patients with immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis).

In patients with liver dysfunction, parenteral iron should only be administered after careful risk/benefit assessment. Parenteral iron administration should be avoided in patients with hepatic dysfunction where iron overload is a precipitating factor, in particular Porphyria Cutanea Tarda (PCT). Careful monitoring of iron status is recommended to avoid iron overload.

Pregnancy and lactation

Data on a limited number of exposed pregnancies indicated no adverse effects of Venofer on pregnancy or on the health of the foetus/newborn child. No well-controlled studies in pregnant women are available to date. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Nevertheless, risk/benefit evaluation is required.

Venofer should only be used in pregnant women in whom oral iron is ineffective or cannot be tolerated and the level of anaemia is judged sufficient to put the mother or foetus at risk.

Pregnancy first trimester: see contraindications

Non metabolized Venofer is unlikely to pass into the mother's milk. No well-controlled clinical studies are available to date. Animal studies do not indicate direct or indirect harmful effects to the nursing child.

Effects on Ability to Drive and Use Machines

In the case of symptoms of dizziness, confusion or light headedness following the administration of Venofer, patients should not drive or use machinery until the symptoms have ceased.

Overdose

Overdosage can cause acute iron overloading which may manifest itself as haemosiderosis. Overdosage should be treated with supportive measures and, if required, an iron chelating agent.

Interaction with other medicaments and other forms of interaction

As with all parenteral iron preparations, Venofer should not be administered concomitantly with oral iron preparation since the absorption of oral iron is reduced. Therefore, oral iron therapy should be started at least 5 days after the last injection of Venofer.

Posology

The cumulative dose of Venofer must be calculated for each patient individually and must not be exceeded.

Calculation of dosage

The total cumulative dose of Venofer, equivalent to the total iron deficit (mg), is determined by the hemoglobin level (Hb) and body weight (BW). The dose of Venofer must be individually calculated for each patient according to the total iron deficit calculated with the following Ganzoni formula, for example:

$$\text{Total iron deficit [mg]} = \text{BW [kg]} \times (\text{target Hb} - \text{actual Hb}) [\text{g/dl}] \times 2.4^* + \text{storage iron [mg]}$$

Below 35 kg BW:

Target Hb = 13 g/dl and storage iron = 15 mg/kg BW

35 kg BW and above:

Target Hb = 15 g/dl and storage iron = 500 mg

*Factor 2.4 = 0.0034 (iron content of Hb = 0.34%) x 0.07 (blood volume = 7% of BW) x 1000 (conversion of [g] to [mg]) x 10

$$\text{Total Venofer to be administered (in ml)} = \frac{\text{Total iron deficit [mg]}}{20 \text{ mg iron/ml}}$$

Total amount of Venofer to be administered according to body weight, actual Hb level and target Hb level*:

BW	Total Venofer (20 mg iron per ml) to be administered			
	Hb 6.0 g/dl	Hb 7.5 g/dl	Hb 9.0 g/dl	Hb 10.5 g/dl
30 kg	47.5 ml	42.5 ml	37.5 ml	32.5 ml

35 kg	62.5 ml	57.5 ml	50 ml	45 ml
40 kg	67.5 ml	60 ml	55 ml	47.5 ml
45 kg	75 ml	65 ml	57.5 ml	50 ml
50 kg	80 ml	70 ml	60 ml	52.5 ml
55 kg	85 ml	75 ml	65 ml	55 ml
60 kg	90 ml	80 ml	67.5 ml	57.5 ml
65 kg	95 ml	82.5 ml	72.5 ml	60 ml
70 kg	100 ml	87.5 ml	75 ml	62.5 ml
75 kg	105 ml	92.5 ml	80 ml	65 ml
80 kg	112.5 ml	97.5 ml	82.5 ml	67.5 ml
85 kg	117.5 ml	102.5 ml	85 ml	70 ml
90 kg	122.5 ml	107.5 ml	90 ml	72.5 ml

*Below 35 kg BW : Target Hb = 13 g/dl

35 kg BW and above : Target Hb =15 g/dl

To convert Hb (mM) to Hb (g/dl), multiply the former by 1.6.

If the total necessary dose exceeds the maximum allowed single dose, then the administration must be divided. If no response of the hematological parameters is observed after 1 to 2 weeks, the original diagnosis should be reconsidered.

Posology

Adults

5-10 ml of Venofer (100-200 mg iron) 1 to 3 times a week.

For administration time and dilution ratio see "Method of administration".

Pediatric Patients (2 Years of Age and Older) with Hemodialysis Dependent-Chronic Kidney Disease (HDD-CKD) for Iron Maintenance Treatment

For iron maintenance treatment: Administer Venofer at a dose of 0.5 mg/kg, not to exceed 100 mg per dose, every two weeks for 12 weeks given undiluted by slow intravenous injection over 5 minutes or diluted in 0.9% NaCl at a concentration of 1 to 2 mg/mL and administered over 5 to 60 minutes. Do not dilute to concentrations below 1 mg/mL. Venofer treatment may be repeated if necessary.

The dosing for iron replacement treatment in pediatric patients with HDD-CKD has not been established.

Method of administration

Venofer must only be administered by the intravenous route. This may be a slow intravenous injection or by an intravenous drip infusion. However, administration by intravenous drip infusion is the preferred route of administration as this may help to reduce the risk of hypotensive episodes and paravenous leakage. Before administering the first dose to new patient, a test dose of Venofer should be given.

Facilities for cardio-pulmonary resuscitation must be available when administering Venofer because allergic or anaphylactoid reactions and hypotensive episodes may occur.

Venofer is a strongly alkaline solution, and must never be administered by the subcutaneous or intramuscular route. Paravenous leakage must be avoided because leakage of Venofer at the injection site may lead to pain, inflammation, tissue necrosis, sterile abscess, and brown discoloration of the skin.

Intravenous drip infusion

Venofer must only be diluted in sterile 0.9% m/V sodium chloride (NaCl) solution. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Venofer dose (mg of iron)	Venofer dose (ml of Venofer)	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum infusion time
50 mg	2.5 ml	50 ml	8 minutes
100 mg	5 ml	100 ml	15 minutes
200 mg	10 ml	200 ml	30 minutes

For stability reasons, dilution to lower Venofer concentrations are not permissible.

Intravenous injection

Venofer must be administered by slow intravenous injection at a rate of 1 ml undiluted solution per minute and not exceeding 10 ml (200 mg iron) per injection.

Injection into venous line of dialysis machine

Venofer may be administered during a hemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

Incompatibilities

Venofer must only be mixed with 0.9% of sodium chloride solution. No other intravenous dilution solutions and therapeutics agents should be used as there is the potential for the precipitation and/or interaction. The compatibility with containers other than glass, polyethylene and PVC is not known.

Shelf life

Shelf life in the product as packaged for sale is 2 years.

Shelf life after first opening the container:

From a microbiological point of view, the product should be used immediately.

Shelf life after dilution with 0.9% sodium chloride solution:

Chemical and physical in-use stability has been demonstrated for 12 hours at room temperature. From a microbiological point of view, the product should be used immediately.

Special precautions for storage

Store in original carton. Store below 30°C.

Do not freeze.

Instruction for use/handling

Ampoules should be visually inspected for sediment and damage before use. Only those with sediment free and homogenous solution must be used.

See also shelf life.

Package form

Ampoules (5 mL) containing 100 mg of iron: 5

Reg. No. DK10355200143A1

Manufactured by:

Siegfried Hameln GmbH

Langes Feld 13

31789 Hameln

Germany

For:

Vifor (International) Inc.

St. Gallen, Switzerland

Imported by:

PT. COMBIPHAR

Bandung Barat, Indonesia

**HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY**

Informasi Obat untuk Pasien
Venofer Injeksi, Ampul 5 ml, Zat Besi (sebagai Iron Sucrose) 100 mg

Brosur ini memberikan informasi penting tentang penggunaan VENOFER. Anda juga harus berbicara dengan dokter atau apoteker Anda jika Anda menginginkan informasi lebih lanjut atau jika Anda memiliki kekhawatiran atau pertanyaan tentang penggunaan VENOFER.

Apa isi brosur ini?

1. Mengapa saya menggunakan VENOFER?
2. Apa yang harus saya ketahui sebelum menggunakan VENOFER?
3. Bagaimana cara menggunakan VENOFER?
4. Apakah ada efek sampingnya?
5. Bagaimana menyimpan VENOFER?
6. Isi dari kemasan dan informasi lain

1. Mengapa saya menggunakan VENOFER?

VENOFER mengandung bahan aktif iron sucrose. VENOFER menyediakan sumber zat besi yang dapat membantu mengisi kekurangan zat besi pada pasien dewasa dengan kondisi:

- Jika secara klinis dibutuhkan cepat.
- Pasien yang intoleran dengan terapi oral atau pasien yang tidak patuh pada masa pengobatan.
- Jika terapi oral tidak efektif.

VENOFER digunakan untuk perawatan pemeliharaan zat besi pada pasien anak-anak (di atas 2 tahun) dengan Penyakit Ginjal Kronis yang menjalani Hemodialisa.

Tanyakan kepada dokter Anda jika Anda memiliki pertanyaan tentang mengapa VENOFER diresepkan untuk Anda. Obat ini hanya tersedia dengan resep dokter.

2. Apa yang harus saya ketahui sebelum menggunakan VENOFER?

Jangan gunakan VENOFER jika:

- Anda alergi terhadap VENOFER, bahan aktif atau bahan tambahan lain pada produk ini.
- Anda mengalami Anemia yang bukan disebabkan kekurangan besi.
- Anda mengalami kelebihan besi atau adanya gangguan penggunaan zat besi dalam tubuh.
- Anda memiliki riwayat penyakit asma, eksim, atau bakat alergi lainnya
- Anda hamil trimester pertama
- Anda memiliki riwayat penyakit sirosis atau hati atau kadar serum transaminase yang lebih tinggi tiga kali dari batas normal.
- Anda menderita infeksi akut atau kronis, mengingat penggunaan besi melalui parenteral dapat memperburuk infeksi bakteri atau virus.

Anda harus menyadari bahwa:

- Sediaan zat besi yang diberikan secara parenteral dapat menyebabkan reaksi alergi yang dapat berakibat fatal. Oleh karena itu, fasilitas resusitasi jantung-paru harus tersedia.
- Jika terjadi reaksi alergi yang serius, pemberian VENOFER harus segera dihentikan. Tindakan suportif seperti pemberian adrenalin intramuskular dan tindakan lainnya dilakukan sesuai dengan prosedur resusitasi jantung-paru yang ditetapkan RS atau klinik.
- Reaksi alergi ringan ditangani dengan menghentikan pemberian VENOFER dan memberikan antihistamin. Episode hipotensi dapat timbul jika injeksi diberikan terlalu cepat. Pasien dengan kapasitas pengikatan zat besi yang rendah dan/atau defisiensi asam folat berisiko mengalami alergi.
- Pada kasus kebocoran paravena yang tidak disengaja, dan jika jarum masih ada, bilas dengan sedikit larutan 0.9% natrium klorida.
- Adanya peningkatan risiko reaksi hipersensitivitas terhadap sediaan parenteral kompleks besi dapat terjadi pada pasien dengan kondisi imun dan inflamasi (mis: penyakit auto imun yang menyebabkan peradangan pada beberapa bagian tubuh (*lupus eritematosus* sistemik) dan peradangan pada sendi (*rheumatoid arthritis*)).
- Pada pasien dengan gangguan fungsi hati, sediaan parenteral zat besi hanya diberikan dengan pertimbangan risiko/manfaatnya. Pemberian zat besi secara parenteral harus dihindari pada pasien dengan gangguan fungsi hati dimana kelebihan zat besi merupakan faktor pencetusnya, khususnya kelainan genetik pada pembentukan sel darah merah (*Porphyria Cutanea Tarda* (PCT)). Pemantauan status zat besi secara cermat sangat direkomendasikan untuk mencegah kelebihan zat besi.

Penggunaan saat hamil dan menyusui

Beritahukan dokter Anda jika Anda sedang hamil; sedang program hamil atau sedang menyusui.

VENOFER hanya diberikan pada wanita hamil jika pemberian zat besi secara oral tidak efektif atau tidak dapat ditoleransi, dan kriteria anemia dinilai cukup membahayakan kondisi ibu atau janin.

VENOFER yang tidak dimetabolisme kecil kemungkinannya untuk masuk ke dalam ASI. Tidak ada studi klinis terkontrol yang tersedia saat ini. Penelitian pada hewan tidak menunjukkan efek berbahaya langsung atau tidak langsung terhadap anak yang menyusui.

Efek pada pengemudi dan menjalankan mesin

Pada kasus dengan gejala pusing atau sakit kepala ringan setelah diberikan VENOFER, disarankan untuk tidak mengemudi atau menjalankan mesin sampai gejala tersebut hilang.

Penggunaan obat-obatan lain dengan VENOFER

Beritahukan dokter Anda jika Anda sedang mengonsumsi atau baru mengonsumsi obat lain, termasuk obat-obatan yang diperoleh tanpa resep dokter.

Beritahukan dokter Anda, jika Anda mengonsumsi obat-obatan yang mengandung zat aktif berikut:

- Sediaan zat besi oral, karena dapat menurunkan penyerapan zat besi sediaan oral. Konsumsi produk zat besi oral minimal 5 hari setelah injeksi VENOFER selesai diberikan.

3. Bagaimana cara menggunakan VENOFER?

Berapa banyak yang digunakan

Dokter Anda akan menghitung dosis dan berapa lama Anda akan menerima VENOFER. Ini tergantung pada respons Anda terhadap pengobatan. Dokter Anda mungkin mengubah dosis dan frekuensi obat Anda seiring perubahan kondisi Anda.

Bagaimana VENOFER diberikan

- Dokter atau perawat Anda akan menyiapkan obat ini untuk Anda.
- Ampul harus diperiksa secara visual sebelum digunakan untuk melihat adanya sedimen atau kerusakan. Larutan yang bebas sedimen dan homogen yang dapat digunakan.
- VENOFER hanya diberikan melalui infus intravena. Pemberian infus intravena dapat mengurangi risiko episode hipotensi dan kebocoran paravena. Sebelum dosis pertama diberikan pada pasien baru, Anda akan diberikan uji dosis VENOFER terlebih dahulu.
- Fasilitas resusitasi jantung-paru harus tersedia ketika VENOFER diberikan, karena reaksi anafilaktik dan episode hipotensi dapat terjadi.
- VENOFER merupakan larutan yang sangat basa sehingga tidak boleh diberikan melalui subkutan atau intramuscular.
- VENOFER hanya boleh dicampur dengan larutan 0.9% NaCl. Larutan pengenceran intravena dan bahan terapi lainnya tidak boleh digunakan karena terdapat potensi pengendapan dan/atau interaksi.

Jika Anda diberi terlalu banyak VENOFER

- Jika Anda merasa telah diberi terlalu banyak, Anda mungkin memerlukan perhatian medis segera.
- Anda harus melakukan ini meskipun tidak ada tanda-tanda ketidaknyamanan atau keracunan.
- Kelebihan zat besi akut dapat menimbulkan terjadinya akumulasi zat besi pada jaringan tubuh atau disebut *hemosiderosis*.

4. Apakah ada efek sampingnya?

Seperti pada obat lain, VENOFER dapat menyebabkan timbulnya efek samping, meskipun tidak semua orang dapat mengalaminya.

Informasikan kepada Dokter atau Perawat Anda, segera setelah Anda mengetahui efek samping yang terjadi pada Anda seperti di bawah ini:

- Reaksi anafilaktik, sangat jarang terjadi. Namun, ini bisa berakibat fatal.
- Efek samping berikut dilaporkan dengan frekuensi $\geq$ satu persen:
 - Seperti merasakan logam logam pada lidah (*metallic taste*), sakit kepala, mual, muntah, hipotensi, dan reaksi pada tempat injeksi/infus.
- Efek samping berikut dilaporkan lebih jarang terjadi:
 - Kebas/kesemutan (*Paraesthesia*), gangguan perut/pencernaan, nyeri otot, demam, biduran (*uritikaria*), kemerahan (*flushing*), edema/bengkak pada ekstremitas, gangguan pernapasan (*dyspnea*), reaksi anafilaktoid (pseudoalergi), pusing, pruritus, ruam, lemah (*astenia*), kelelahan (*fatigue*), sinkop/pingsan, mengantuk, palpitasi/denyut jantung meningkat, urin berwarna merah (*kromaturia*), nyeri dada, keringat berlebih (*hyperhidrosis*), dan demam (*pyrexia*). Reaksi pada tempat injeksi, radang pada pembuluh darah vena (*phlebitis*) dan spasme vena telah diamati.

- Efek samping berikut masih dalam investigasi:
 - termasuk peningkatan kadar alanin aminotransferase, peningkatan aspartat aminotransferase, peningkatan gamma-glutamyltransferase, peningkatan serum ferritin, dan peningkatan laktat dehidrogenase dalam darah.

Apa yang harus dilakukan

Beri tahu dokter, perawat, atau apoteker Anda jika Anda mengalami hal lain yang mungkin membuat Anda merasa tidak enak badan saat Anda diberi VENOFER, meskipun menurut Anda tidak ada hubungannya dengan obat ini dan tidak merujuk dalam brosur ini.

Efek samping lain yang tidak tercantum di sini mungkin terjadi pada beberapa orang.

Kontak pelaporan efek samping

Apabila ditemukan kejadian tidak diinginkan atau efek samping terkait penggunaan obat ini, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan kejadian tidak diinginkan atau efek samping secara langsung ke PT Combiphar dengan menghubungi Combi Care Center melalui hotline 0800-1-800088 atau WhatsApp di nomor 0818 06800088 atau email combicarecenter@combiphar.com dan/atau kepada Pusat Farmakovigilans BPOM melalui email pv-center@pom.go.id.

5. Bagaimana menyimpan VENOFER?

Jauhkan VENOFER dari jangkauan anak-anak

Jangan gunakan VENOFER jika telah melewati batas tanggal kadaluarsa (cek di label dan kemasan)

Simpan dalam karton original. Simpan dibawah suhu 30°C

Jangan dibekukan

Umur penyimpanan untuk produk VENOFER adalah 2 tahun.

Setelah ampul VENOFER dibuka, maka harus segera digunakan. Setelah pengenceran dengan larutan 0.9% Natrium Klorida, larutan yang diencerkan harus segera digunakan.

6. Isi dari kemasan dan informasi lain

Zat aktif dari VENOFER adalah zat besi (sebagai *Iron Sucrose*).

Tiap ampul (5 mL) mengandung 100 mg zat besi.

Zat tambahan: air untuk injeksi, natrium hidroksida.

No. Reg. DK10355200143A1

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:

Siegfried Hameln GmbH

Langes Feld 13

31789 Hameln

Germany

Untuk:

Vifor (International) Inc.

St Gallen, Switzerland

Diimpor oleh:

PT COMBIPHAR

Bandung Barat, Indonesia