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PABAL
Carbetocin
Solution for injection 100 mcg/ml

QUALITATIVE AND QUANTITATIVE COMPOSITION
Carbetocin 100 micrograms/ml.

Excipients:
L-Methionine, Succinic Acid, Mannitol, Sodium Hydroxide, Water for injections.

PHARMACEUTICAL FORM
Solution for injection.
A clear colourless solution.

THERAPEUTIC INDICATIONS
Prevention of postpartum haemorrhage due to uterine atony

POSOLOGY AND METHOD OF ADMINISTRATION
Posology

- *Caesarean section under epidural or spinal anaesthesia:*
  Withdraw 1 ml of PABAL containing 100 micrograms carbetocin and administer only by intravenous injection, under adequate medical supervision in a hospital.

- *Vaginal delivery:*
  Withdraw 1 ml of PABAL containing 100 micrograms carbetocin and administer by intramuscular injection under adequate medical supervision in a hospital.
  PABAL can also be administered by intravenous injection based on clinical judgement and under adequate medical supervision in a hospital.

Method of administration
Carbetocin must only be administered after delivery of the infant, and as soon as possible after delivery, preferably before the delivery of the placenta.

For intravenous administration carbetocin must be administered slowly, over 1 minute.

PABAL is intended for single use only. No further doses of carbetocin should be administered.

Paediatric population
There is no relevant use of carbetocin in children below 12 years of age.

The safety and efficacy of carbetocin in children and adolescents has not been established.

Currently available data are described in section Clinical efficay and safety but no recommendation on a posology can be made.

CONTRAINDICATIONS

- During Pregnancy and labour before delivery of the infant.

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- Carbetocin must not be used for the Induction of labour.
- Hypersensitivity to carbetocin, oxytocin or any excipients listed in section Excipients.
- Hepatic or renal disease.
- Serious cardiovascular disorders.
- Epilepsy.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Carbetocin is intended for use only at well-equipped specialist obstetrics units with experienced and qualified staff available at all times.

The use of carbetocin at any stage before delivery of the infant is not appropriate because its uterotonic activity persists for several hours. This is in marked contrast to the rapid reduction of effect observed after discontinuation of an oxytocin infusion.

In case of persistent vaginal or uterine bleeding after administration of carbetocin the cause must be determined. Consideration should be given to causes such as retained placental fragments, perineal, vaginal and cervix lacerations, inadequate repair of the uterus, or disorders of blood coagulation.

Carbetocin is intended for single administration only (see posology and method of administration). In case of intravenous administration, It must be administered slowly over 1 minute. In case of persisting uterine hypotonia or atonia and the consequent excessive bleeding, additional therapy with another uterotonic should be considered. There are no data on additional doses of carbetocin or on the use of carbetocin following persisting uterine atony after oxytocin.

Animal studies have shown carbetocin to possess some antidiuretic activity (Vasopressin activity: <0,025 IU/vial) and therefore the possibility of hyponatraemia cannot be excluded, particularly in patients also receiving large volumes of intravenous fluids. The early signs of drowsiness, listlessness and headache should be recognised to prevent convulsions and coma.

In general, carbetocin should be used cautiously in the presence of migraine, asthma and cardiovascular disease or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system. The decision of administering carbetocin can be made by the physician after carefully weighing the potential benefit carbetocin may provide in these particular cases.

No data is available on the use of carbetocin in patients with eclampsia. Patients with eclampsia and preeclampsia should be carefully monitored.

Specific studies have not been undertaken in gestational diabetes mellitus.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

During clinical trials, carbetocin has been administered in association with a number of analgesics, spasmolytics and agents used for epidural or spinal anaesthesia, and no drug interactions have been identified.

Specific interaction studies have not been undertaken.

Since carbetocin is closely related in structure to oxytocin, the occurrence of interactions known to be associated with oxytocin cannot be excluded:
Severe hypertension has been reported when oxytocin was given 3 to 4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal-block anaesthesia.

During combination with ergot-alkaloids, such as methylergometrine, oxytocin and carbetocin may enhance the blood pressure enhancing effect of these agents. If oxytocin or methylergometrine are administered after carbetocin there may be a risk of cumulative exposure.

Since it has been found that prostaglandins potentiate the effect of oxytocin, it is expected that this can also occur with carbetocin. Therefore, it is not recommended that prostaglandins and carbetocin be used together. If they are concomitantly administered, the patient should be carefully monitored.

Some inhalation-anesthetics, such as halothane and cyclopropane may enhance the hypotensive effect and weaken the effect of carbetocin on the uterus. Arrhythmias have been reported for oxytocin during concomitant use.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

Carbetocin is contraindicated during pregnancy and must not be used for the induction of labour (see section Contraindications).

Breastfeeding

No significant effects on milk let-down have been reported during clinical trials. Small amounts of carbetocin have been shown to pass from plasma into breast milk of nursing women (see section Pharmacokinetic properties). The small amounts transferred into colostrum or breast milk after a single injection of carbetocin, and subsequently ingested by the infant are assumed to be degraded by enzymes in the gut. Breast-feeding does not need to be restricted after the use of carbetocin.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Not relevant.

UNDESIRABLE EFFECTS

The adverse events observed with carbetocin during the clinical trials were of the same type and frequency as the adverse events observed with oxytocin.

Intravenous administration – Tabulated summary of adverse reactions*

System Organ Class	Very common ≥ 1/10	Common ≥ 1/100 and < 1/10	Not known (cannot be estimated from the available data)
Blood and the lymphatic system disorders		Anaemia	
Immune system disorders			Hypersensitivity (including anaphylactic reaction)
Nervous system disorders	Headache, tremor	Dizziness	
Cardiac disorders			Tachycardia, bradycardia which can lead to cardiac arrest ***, arrhythmia***, myocardial ischaemia***, and QT prolongation***
Vascular disorders	Hypotension, flushing		
Respiratory, thoracic and mediastinal disorders		Chest pain, dyspnoea	

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Gastrointestinal disorders	Nausea, abdominal pain	Metallic taste, vomiting	
Skin and subcutaneous tissue disorders	Pruritus		
Musculoskeletal and connective tissue disorders		Back pain	
General disorders and administration site conditions	Feeling of warmth	Chills, pain	

* Based on studies in caesarean section
*** Reported with oxytocin (closely related in structure to carbetocin)

In the clinical trials sweating was reported as sporadic cases.

*Intramuscular administration** – Tabulated summary of adverse reactions*

System Organ Class	Uncommon	Rare	Not known (cannot be
	≥ 1/1,000 and <1/100	≥ 1/10,000 and < 1/1,000	estimated from the available data)
Blood and the lymphatic system disorders	Anaemia		
Immune system disorders			Hypersensitivity (including anaphylactic reaction)
Nervous system disorders	Headache, dizziness	Tremor	
Cardiac disorders	Tachycardia		Bradycardia***, arrhythmia***, myocardial ischaemia***, and QT prolongation***
Vascular disorders	Hypotension	Flushing	
Respiratory, thoracic and mediastinal disorders	Chest pain	Dyspnoea	
Gastrointestinal disorders	Nausea, abdominal pain, vomiting		
Skin and subcutaneous tissue disorders		Pruritus	
Musculoskeletal and connective tissue disorders	Back pain, muscular weakness		
Renal and urinary disorders		Urinary retention	
General disorders and administration site conditions	Chills, pyrexia, pain		

** Based on studies in vaginal delivery
*** Reported with oxytocin (closely related in structure to carbetocin)

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Adverse Event Reporting

If you notice any of the adverse reactions mentioned above, or any adverse reactions not listed in this leaflet, please contact your doctor or nurse. You can also report these side effects to Ferring or the national reporting system provided below. Reporting side effects helps to gather more information about the safety of this medication.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No Telp: (021) 50868801
Email: SafetyMailboxIndonesia@ferring.com

Pusat MESO/Farmakovigilans Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan POM RI
Jl. Percetakan Negara 23 Jakarta Pusat, 10560
Email : pv-center@pom.go.id
Web: http://e-meso.pom.go.id/

OVERDOSE

Overdosage of carbetocin may produce uterine hyperactivity whether or not due to hypersensitivity to this agent.

Hyperstimulation with strong (hypertonic) or prolonged (tetanic) contractions resulting from oxytocin overdose can lead to uterine rupture or postpartum haemorrhage.

Overdosage of oxytocin may lead to hyponatraemia and water intoxication in severe cases, especially when associated with excessive concomitant fluid intake. As carbetocin is an analogue of oxytocin, the possibility of a similar event cannot be excluded.

Treatment of overdosage of carbetocin consists of symptomatic and supportive therapy. When signs or symptoms of overdosage occur oxygen should be given to the mother. In cases of water intoxication, it is essential to restrict fluid intake, promote diuresis, correct electrolyte imbalance, and control convulsions that may eventually occur.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Oxytocin and analogues ATC
code: H01BB03

The pharmacological and clinical properties of carbetocin are those of a long acting oxytocin agonist.

Like oxytocin, carbetocin selectively binds to oxytocin receptors in the smooth muscle of the uterus, stimulates rhythmic contractions of the uterus, increases the frequency of existing contractions, and raises the tone of the uterus musculature.

On the postpartum uterus, carbetocin is capable of increasing the rate and force of spontaneous uterine contractions. The onset of uterine contraction following carbetocin is rapid after intravenous or intramuscular administration, with a firm contraction being obtained within 2 minutes.

A single 100 micrograms intravenous or intramuscular dose of carbetocin administered after the delivery of the infant is sufficient to maintain adequate uterine contraction that prevents uterine atony and excessive bleeding comparable with an oxytocin infusion lasting for several hours.

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Clinical efficacy and safety

The efficacy of carbetocin in the prevention of postpartum haemorrhage following vaginal delivery was established in one randomised, active controlled, double-blind trial. In total 29645 subjects were randomised to receive a single intramuscular dose of either carbetocin 100 µg or oxytocin 10 IU. For the primary endpoint of blood loss of ≥500 mL or use of additional uterotonics, similar rates were obtained in both treatment groups (carbetocin: 2135 subjects, 14.47%; oxytocin: 2122 subjects, 14.38%; relative risk [RR] 1.01; 95% CI: 0.95 to 1.06), demonstrating noninferiority of carbetocin compared with oxytocin with regard to the primary endpoint.

Paediatric population:
In the clinical development of carbetocin for the prevention of postpartum haemorrhage following vaginal delivery, 151 women between 12 to 18 years were included but no recommendation on a posology can be made at this time.

PHARMACOKINETIC PROPERTIES
The pharmacokinetics of carbetocin have been investigated in healthy female subjects. Carbetocin shows biphasic elimination after intravenous administration with linear pharmacokinetics in the dose range of 400 to 800 micrograms. The median terminal elimination half-life is 33 minutes after intravenous administration and 55 minutes after intramuscular administration. After intramuscular administration, peak concentrations are reached after 30 minutes and the mean bioavailability is 77%. The mean volume of distribution at pseudo-equilibrium (Vz) is 22 L. Renal clearance of the unchanged form is low, with <1% of the injected dose excreted unchanged by the kidney.

After intramuscular administration of 70 µg carbetocin in 5 healthy nursing mothers, carbetocin concentrations were detectable in milk samples. Mean peak concentrations in milk were below 20 pg/mL, which was approximately 56 times lower than in plasma at 120 min

PRECLINICAL SAFETY DATA
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicology, genotoxicity and local tolerance. A reproductive toxicity study in rats with daily drug administration from parturition to day 21 of lactation, showed a reduction in offspring body weight gain. No other toxic effects were observed. The indication did not warrant studies on fertility or embryotoxicity.

Carcinogenicity studies have not been performed with carbetocin due to the single dose nature of the indication.

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

SHELF LIFE
3 years.
Shelf life after first opening the container: After first opening the vial, the solution should be used immediately.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

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STORAGE
Keep vials in the outer carton, in order to protect from light. Store below 30°C. Do not freeze.

Keep medicines out of reach of children.

Do not use the medicine after the expiry date stated on the package.
SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Only particle free, clear solutions should be used.

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

PACKING SIZE
Box of 5 vials @ 1mL (Reg. No.: DKIXXXXXXXXX)

MANUFACTURED AND RELEASED BY
Ferring GmbH
Kiel, Germany

SECONDARY PACKAGING BY
Ferring-Léčiva, a.s.
Ke Skále Vestec, Czech Republic

IMPORTED BY
PT Ferring Pharmaceuticals Industry Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

DATE OF REVISION
05 April 2026

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Informasi untuk pasien
Pabal 100 mcg/ml larutan untuk injeksi
Carbetocin

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda diberikan suntikan Pabal karena leaflet ini mengandung informasi penting untuk Anda.
- Simpanlah leaflet ini, sebab Anda mungkin perlu membacanya lagi dikemudian hari.
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, bidan atau perawat Anda.
- Jika Anda mengalami efek samping, beritahukan dokter, bidan atau perawat Anda. Termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini. Lihat bagian 4.

Apa isi leaflet ini?

1. Apa itu Pabal dan apa kegunaannya
Pabal digunakan untuk mecegah pendarahan pasca persalinan pada wanita yang baru saja melahirkan, baik melalui operasi caesar maupun persalinan pervaginam.
Pada beberapa wanita, setelah operasi caesar, rahim tidak berkontraksi (menyusut) dengan cukup cepat sehingga meningkatkan risiko terjadinya perdarahan lebih banyak pendarahan dari biasanya. Pabal bekerja dengan merangsang kontraksi rahim sehingga dapat membantu mengurangi risiko pendarahan. Bahan aktif dalam Pabal adalah carbetocin, yaitu senyawa yang menyerupai oksitosin, suatu zat alami yang diproduksi tubuh untuk merangsang kontraksi rahim selama proses persalinan.

2. Apa yang perlu Anda ketahui sebelum menggunakan Pabal

Pabal tidak boleh diberikan sampai setelah bayi lahir.
Sebelum memberikan Pabal, dokter Anda perlu mengetahui tentang kondisi kesehatan yang Anda miliki. Anda juga harus memberi tahu dokter tentang gejala-gejala baru yang muncul ketika Anda diobati dengan Pabal.

Pabal tidak boleh digunakan:
- Jika Anda alergi terhadap carbetocin atau zat lain yang terkandung dalam obat ini (lihat bagian 6)
- Jika Anda memiliki penyakit jantung yang serius
- Jika Anda pernah mengalami reaksi alergi terhadap oksitosin (obat ini dapat diberikan secara infus atau injeksi selama atau setelah persalinan)

Jika Anda mengalami salah satu keadaan di atas, segera beritahukan kepada dokter Anda.

Dokter Anda perlu berhati-hati saat menggunakan Pabal
- Jika Anda terkena migrain
- Jika Anda menderita asma
- Jika Anda memiliki masalah dengan jantung atau sirkulasi darah Anda (seperti misalnya tekanan darah tinggi)

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- Jika Anda memiliki kondisi kesehatan lainnya
- Jika anda mengalami pre-eklampsiadan eklampsia penggunaan PABAL harus dilakukan secara hati-hati

Jika Anda mengalami hal ini, segera beritahu dokter Anda.

Anak-anak: Tidak relevan

Obat lain dan Pabal
Beritahukan dokter apabila Anda sedang menggunakan, baru saja menggunakan atau mungkin menggunakan obat lain, termasuk obat yang dibeli tanpa resep dokter.

Interaksi obat dan makanan yang harus dihindari saat menggunakan obat ini
Beritahukan kepada dokter atau bidan semua obat yang sedang Anda gunakan, termasuk obat resep, obat bebas, vitamin, atau produk herbal. Beberapa obat dapat berinteraksi dengan carbetocin dan memengaruhi keamanannya.

Obat-obatan yang dapat berinteraksi dengan carbetocin antara lain:

1. Obat vasokonstriktor (obat yang meningkatkan tekanan darah) Contoh: obat yang diberikan sebelum anestesi caudal/epidural.
   Efek interaksi: dapat menyebabkan peningkatan tekanan darah yang berat bila digunakan beberapa jam sebelum obat seperti oksitosin; risiko ini juga dapat terjadi dengan carbetocin.
2. Obat golongan ergot
   Contoh: metilergometrin (methylergometrine).
   Efek interaksi: dapat meningkatkan tekanan darah, dan bila diberikan setelah carbetocin dapat terjadi penumpukan efek.
3. Prostaglandin
   Contoh: misoprostol, dinoprostone, carboprost.
   Efek interaksi: dapat memperkuat efek carbetocin pada kontraksi rahim.
   Catatan: penggunaan bersamaan tidak dianjurkan kecuali dengan pemantauan ketat oleh tenaga kesehatan.
4. Obat bius inhalasi (gas anestesi) Contoh: halothane, cyclopropane.
   Efek interaksi: dapat melemahkan efek carbetocin dan meningkatkan risiko penurunan tekanan darah atau gangguan irama jantung.
5. Obat lain yang diberikan bersama analgesik atau anestesi epidural/spinal
   Efek interaksi: tidak ditemukan interaksi yang bermakna dalam uji klinis, tetapi tetap perlu diinformasikan kepada tenaga kesehatan.

Makanan dan minuman
Berdasarkan informasi pada SPC, tidak terdapat makanan atau minuman tertentu yang diketahui berinteraksi dengan carbetocin. Namun, tetap informasikan jika Anda mengonsumsi suplemen atau produk herbal.

Kehamilan dan menyusui
Pabal tidak boleh digunakan selama kehamilan, tetapi dapat diberikan setelah proses melahirkan melalui operasi caesar.
Sejumlah kecil carbetocin terbukti masuk ke dalam saluran ASI, tetapi diasumsikan akan terurai dalam usus bayi.

3. Bagaimana cara pemberian Pabal

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Operasi Caesar
100 mikrogram PABAL yang mengandung Carbetocin hanya dapat diberikan melalui suntikan intravena, di bawah pengawasan medis yang memadai di rumah sakit.

Persalinan Pervaginal
100 mikrogram PABAL yang mengandung Carbetocin hanya dapat diberikan melalui suntikan intravena atau intramuskular, di bawah pengawasan medis yang memadai di rumah sakit.

Jika seseorang diberi Pabal terlalu banyak
Jika Anda secara tidak sengaja diberi Pabal terlalu banyak, akan mengakibatkan rahim Anda berkontraksi cukup kuat dan menyebabkan pendarahan berat. Anda mungkin akan menderita kantuk, lesu dan sakit kepala, yang disebabkan oleh penumpukan cairan di tubuh Anda. Sehingga Anda harus diobati dengan obat lain, dan mungkin akan dioperasi.

4. Efek samping yang mungkin terjadi

Seperti obat lainnya, Pabal dapat memberikan efek samping, yang mungkin tidak semua orang akan mendapatkannya.

Pemberian secara intravena
Efek samping yang paling sering dan mempengaruhi setidaknya ≥1/10 wanita yang diobati dengan PABAL untuk pemerian secara Intravena, termasuk:

- Sakit kepala
- Tremor
- Tekanan darah rendah
- kemerahan pada kulit
- Mual
- Sakit pada perut abdomen
- Gatal pada kulit
- Sensasi panas

Efek samping yang paling sering dan mempengaruhi setidaknya ≥1/100 dan <1/10 wanita yang diobati dengan PABAL untuk pemerian secara Intravena, termasuk:

- Kekurangan sel darah merah
- Pusing
- Sakit dada
- Sesak nafas
- Rasa metallic
- Muntah
- Sakit pinggang
- Menggigil, nyeri

Pemberian secara intramuskular
Efek samping lainnya, yang dapat mempengaruhi ≥ 1/1000 wanita dan <1/100 wanita untuk yang diberikan secara Intramuskular meliputi:

- Kekurangan sel darah merah
- Sakit kepala
- Pusing
- Detak jantung terasa lebih cepat
- Tekanan darah rendah

- Sakit dada
- Mual
- Sakit pada perut abdomen
- Muntah
- Sakit punggung
- Kelemahan otot
- Menggigil, demam, nyeri

Efek samping lainnya, yang dapat mempengaruhi antara ≥ 1/10,000 and < 1/1,000 wanita, untuk yang diberikan secara Intramuskular meliputi:

- Tremor
- Kemerahan pada muka
- Sesak nafas
- Gatal pada kulit
- Retensi urin

Tak jarang beberapa wanita mungkin mengalami detak jantung cepat atau berkeringat.
Pabal dapat menyebabkan penumpukan air di dalam tubuh yang bisa menyebabkan kantuk, lesu dan sakit kepala.

Pelaporan Kejadian yang Tidak Diinginkan (Adverse Event Reporting)
Jika Anda mengalami salah satu reaksi yang tidak diinginkan seperti yang disebutkan di atas, atau reaksi yang tidak tercantum dalam leaflet ini, harap segera hubungi dokter atau perawat Anda. Anda juga dapat melaporkan efek samping tersebut kepada Ferring atau sistem pelaporan nasional yang tercantum di bawah ini. Pelaporan efek samping membantu mengumpulkan lebih banyak informasi mengenai keamanan obat ini.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No. Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

5. Bagaimana cara menyimpan Pabal

Simpan vial Pabal dalam karton aslinya agar terlindung dari cahaya. Simpanlah di bawah suhu 30ºC.
Jangan dibekukan.
Hanya larutan yang bening dan bebas dari partikel yang boleh digunakan.
Pabal tidak boleh digunakan setelah tanggal kadaluwarsa yang tercetak pada karton dan vialnya.
Pabal harus dijauhkan dari pandangan dan jangkauan anak-anak.

6. Isi kemasan dan informasi lainnya

Apa isi Pabal?
Zat aktif adalah Carbetocin. Setiap mililiter mengandung 100 mikrogram carbetocin. Bahan lainnya adalah L-metionin, asam suksinat, manitol, natrium hidroksida dan air untuk injeksi.

Tampilan Pabal dan isi dari kemasan
Pabal berbentuk larutan bening tak berwarna untuk injeksi intravena, disertakan dalam kemasan karton berisi lima vial @ 1ml.

Pabal hanya dapat digunakan di unit spesialis kandungan & kebidanan dengan peralatan lengkap.

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Code	PABARTS-I(PIL)-ID-04.01	
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Submission	☐ NDA ☐Renewal ☒Variation change detail no.:	
Code of previous version	PABARTS-I(PIL)-ID-03.01	
Changes	Change Secondary Packaging and Releasing Site	
Reference	☒CCDS version: CCDS V.4 ☐ Core PIL version:	☐ SPC country/version/date: ☐ LAC no.:
Name & Date	HINI, 5 April 2026	

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Tangerang Selatan – Indonesia

HARUS DENGAN RESEP DOKTER

Leaflet ini terakhir direvisi pada bulan 05 April 2026