


REAMBERIN® 1.5 % solution for infusion		
ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
a. Package Insert for health professionals		

Package Insert for health professionals

Reamberin®

Meglumine sodium succinate (6.00 g per 400 mL)

1.5 % solution for infusion

BRAND NAME: Reamberin®

DOSAGE FORM: solution for infusion

COMPOSITION:

	400 mL
Active ingredient	
Meglumine sodium succinate	6.00 g
obtained by mixing of:	
Succinic acid	2.112 g
Meglumine	3.490 g
Excipients	
Sodium chloride	2.40 g
Potassium chloride	0.12 g
Magnesium chloride hexahydrate (as anhydrous)	0.048 g
Sodium hydroxide	0.7152 g
Succinic acid	up to pH 6.0 – 7.0
Water for injections	up to 400 mL

Ion composition per 400 mL:

Sodium ion	58.8 mmol
Potassium ion	1.608 mmol
Magnesium ion	0.504 mmol
Chloride ion	43.6 mmol
Succinate ion	18.4 mmol
Meglumine ion	17.9 mmol

Theoretical osmolarity **353** mOsm/L

DESCRIPTION: A clear colorless solution.

THERAPEUTIC CATEGORY: Solutions affecting the electrolyte balance.

ATC CODE: B05BB.

INDICATIONS


Reamberin® is used as an antioxidant for supporting treatment of adult patients with acute viral hepatitis, purulent peritonitis, and for children over 1 year with rotavirus infection.

ADMINISTRATION AND DOSAGE

In adults Reamberin® should be administered intravenously by continuous infusion at a rate of 1 – 4.5 mL/min (up to 90 drops/min). For adults the daily dose is 400 – 800 mL.

Infusion speed and dosage are estimated based on patient condition.

The treatment course is up to 10 days.

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ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
a. Package Insert for health professionals		

In children over 1 year Reamberin® should be administered intravenously by continuous infusion at a rate of 1 – 4 mL/min (up to 80 drops/min). For children the daily dose is 6 – 10 mL/kg of body weight, not to exceed 400 mL.

The treatment course is up to 7 days.

In the case of missing the dose it is recommended to continue therapy on the next day in the same dosage. The treatment course in this case can be extended.

Special groups of patients

In elderly patients

Special clinical studies for elderly patients have not been carried out.

In patients with renal insufficiency

Special clinical studies for patients with renal insufficiency have not been carried out.

CONTRAINDICATIONS

- Known hypersensitization to Meglumine sodium succinate and/or any of the excipients,
- Traumatic brain edema,
- Acute renal failure,
- Chronic kidney disease (glomerular filtration rate less than 15 mL/min/1.73 m²),
- Pregnancy,
- Breastfeeding.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Reamberin® should be used with great care in patients with alkalosis and renal insufficiency.

Content of Potassium in the medicinal product: 4.02 mmol/L. This should be considered in patients with reduced renal function and in patients on potassium-restricted diet.

Content of Sodium in the medicinal product: 147 mmol/L. This should be considered in patients on sodium-restricted diet.

A decrease in plasma glucose level and alkalization of urine can occur since the medicinal product promotes aerobic respiration in the organism. In patients with diabetes or impaired glucose tolerance, monitoring of blood glucose level is required.


Should color change and precipitate occur, the use of medicinal product is not allowed.

DRUG INTERACTIONS

Reamberin® is compatible with antibiotics, water-soluble vitamins, and glucose solutions.

Reamberin® is compatible with medicinal products, containing phosphates, sulfates or tartrates.

Do not recommend mixing of Reamberin® in one bottle with other preparation. Simultaneous intravenous administration of Reamberin® and calcium preparations is prohibited due to possible precipitation of calcium succinate.

REAMBERIN[®] 1.5 % solution for infusion		
ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
a. Package Insert for health professionals		

PREGNANCY AND LACTATION

Reamberin[®] is not recommended during pregnancy and breastfeeding due to the absence of clinical studies in these groups of patients.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE


There is no proven influence of the medicinal product on ability to drive or operate machinery. To drive and operate machinery is not recommended during the course of treatment with Reamberin[®].

SIDE EFFECTS

If given too fast the following adverse drug reactions can be developed classified according to their frequency of development as follows:

- *very common (frequency of adverse drug reaction is $\geq 1/10$);*
- *common (frequency of adverse drug reaction is $\geq 1/100 - < 1/10$);*
- *uncommon (frequency of adverse drug reaction is $\geq 1/1000 - < 1/100$);*
- *rare (frequency of adverse drug reaction is $\geq 1/10000 - < 1/1000$);*
- *very rare (frequency of adverse drug reaction is $< 1/10000$);*
- *rate is unknown (frequency of adverse drug reaction can't be determined on the basis of the obtained data).*

SOC	Frequency of adverse drug reactions	Adverse drug reactions
Systemic disturbance and local injection site abnormalities	very rare	hyperthermia, shivering, sweating, weakness, local injection site irritation, edema, hyperaemia, phlebitis
Immune disorders	very rare	allergy, angioedema, anaphylactic shock
Skin and subcutaneous tissue disorders	very rare	allergic rash, hives, itch
Respiratory disorders, thoracic organs and mediastinal disorders	very rare	dyspnea, dry cough
Cardiac disorders	very rare	tachycardia, palpitations, dyspnea, cardiac pain, chest pain
Vascular disorders	very rare	arterial hypotension/hypertension, the short-term reactions in forms of heat sensation and upper body erythema
Gastrointestinal disorders	very rare	nausea, vomiting, metallic taste in the mouth, abdominal pain, diarrhea
Nervous system disorders	very rare	dizziness, headache, convulsions, tremor, paresthesia, agitated, anxiety

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ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
a. Package Insert for health professionals		

To avoid adverse drug reactions, it is recommended to comply with the dosing regimen and the rate of medicinal product administration.

If adverse drug reactions occur, the rate of infusion should be lowered.

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 (as detailed below).

<u>Indonesia</u>	PT Pyridam Farma, Tbk Pharmacovigilance Team Email: pv.safety@pyfa.co.id or Pharmacovigilance Centre/MESO Nasional BPOM RI c.q Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor, dan Zat Adiktif Through post : Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560 Email: pv-center@pom.go.id Phone : +62-21- 4244691 Ext. 1079 Fax : +61-21-4245523 Website: http://e-meso.pom.go.id/
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OVERDOSE AND TREATMENT

No cases of overdose with Reamberin[®] were registered or reported. Due to its rapid utilization in organism the overdose with Reamberin[®] is unlikely. Do not use Reamberin[®] in higher doses than recommended.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Reamberin[®] possesses anti-hypoxic and antioxidant properties, rendering positive effect on aerobic processes in the cell, reducing free radical generation, restoring cell action potential and promoting recycling of fatty acids and glucose by cells.

Reamberin[®] activates enzymatic processes of the Krebs cycle and promotes recycling of fatty acids and glucose by cells, normalizes acid-base balance and blood gas structure.

Reamberin[®] has a moderate diuretic effect.

Pharmacokinetics


During intravenous administration Reamberin[®] is quickly utilized and not accumulated in the organism.

HOW SUPPLIED

1.5 % solution for infusion.

400 mL of Reamberin[®] per clear glass bottle, sealed with rubber closure and combined aluminum-plastic cap overseal.

Each bottle is labeled. Each labeled bottle with enclosed two-sided package leaflet, consisted of patient's information leaflet and package insert for health professionals, are packed into one carton package. Tamper-evident sticker is allowed at package.

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ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
a. Package Insert for health professionals		

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL

If you have unused or expired Reamberin[®] you should dispose of the medicine in the following manner. Please open a bottle, dispose of the content via wastewater and the glass bottle via special household waste for glass.

TERMS AND STORAGE

- Shelf life: 5 years.
- Store at temperature below 30 °C.
- Administration of the medicinal product with expired date is prohibited.

Prescription only medicine.


Manufactured by: “Scientific Technological Pharmaceutical Firm “POLYSAN” Ltd. (“STPF “POLYSAN” Ltd.). Lit. A, Building 2, 72 Salova Street, Saint Petersburg, 192102, Russia. Telephone: (812) 448-22-22.

HARUS DENGAN RESEP DOKTER

Registered by: PT. Pyridam Farma Tbk. Sinarmas Land Plaza Sudirman, 12th Floor, Jl. Jendral Sudirman Kav.21, Kel. Karet, Kec. Setiabudi, Kota Adm. Jakarta Selatan, DKI Jakarta 12920, Indonesia

Reg. number: DKI2161600149A1

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REAMBERIN[®] Solution for Infusion		
ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
b. Patient Information Leaflet (PIL)		

Informasi Produk untuk Pasien

(Reamberin[®] 1,5 % larutan untuk infus)
Meglumine sodium succinate (6,00 g per 400 mL)

Baca isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini mengandung informasi yang penting bagi Anda.

- Simpan leaflet ini. Anda mungkin perlu membaca lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter anda.
- Jika Anda mengalami efek samping, bicarakan dengan dokter anda. Ini termasuk efek samping yang mungkin tidak tercantum dalam leaflet ini.

Apa saja yang ada pada leaflet ini

1. Apakah Reamberin[®] 1,5 % larutan untuk infus dan apa kegunaannya
2. Apa yang perlu Anda ketahui sebelum Anda menerima Reamberin[®] 1,5 % larutan untuk infus
3. Bagaimana cara penggunaan Reamberin[®] 1,5 % larutan untuk infus
4. Kemungkinan efek samping
5. Bagaimana cara penyimpanan Reamberin[®] 1,5 % larutan untuk infus
6. Isi kemasan dan informasi lainnya

1. Apakah Reamberin[®] 1,5% larutan untuk infus dan apa kegunaannya

Reamberin[®] adalah 1,5 % larutan untuk infus. Larutan jernih dan tidak berwarna. Reamberin[®] 400 mL dikemas dalam botol kaca. Setiap dus berisi 1 botol dilengkapi dengan informasi produk.


Zat aktif Reamberin adalah Meglumine sodium succinate. Kelas terapi Reamberin adalah larutan yang mempengaruhi keseimbangan elektrolit.

Reamberin[®] digunakan sebagai antioksidan untuk terapi suportif pada orang dewasa dengan hepatitis virus akut, peritonitis purulenta, dan untuk anak-anak di atas 1 tahun dengan infeksi rotavirus.

2. Apa yang perlu Anda ketahui sebelum Anda menerima Reamberin[®] 1,5 % larutan untuk infus

Jangan menggunakan Reamberin[®] jika anda:

- memiliki sensitif atau alergi terhadap komponen obat ini,
- memiliki edema otak traumatis,
- mengalami gagal ginjal akut,
- memiliki penyakit ginjal kronis (laju filtrasi glomerulus kurang dari 15 mL/menit/1,73 m²)
- sedang hamil,
- sedang menyusui.

REAMBERIN[®] Solution for Infusion		
ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
b. Patient Information Leaflet (PIL)		

Jangan menerima Reamberin[®] jika Anda:

- diberikan preparat kalsium. Pemberian intravena Reamberin[®] secara simultan dengan preparat kalsium dilarang karena adanya kemungkinan presipitasi kalsium suksinat.

Mengonsumsi obat lain

Beritahu dokter Anda jika Anda mengonsumsi obat lain, baru saja mengonsumsi atau memulai mengonsumsi obat lain

Reamberin[®] kompatibel dengan antibiotik, vitamin yang larut dalam air, dan larutan glukosa.

Reamberin[®] kompatibel dengan obat-obatan yang mengandung fosfat, sulfat atau tartrat.

Sebelum menggunakan Reamberin[®], tanyakan pada dokter jika anda:

- memiliki alkalosis (peningkatan pH darah karena akumulasi zat alkali);
- memiliki gagal ginjal
- memiliki diabetes mellitus atau pengurangan toleransi glukosa (pemantauan berkala konsentrasi glukosa darah diperlukan);
- menjalankan diet kalium yang ketat
- menjalankan diet natrium yang ketat

Efek terhadap kemampuan menyetir dan menggunakan mesin

Tidak dianjurkan untuk menyetir dan mengoperasikan mesin selama perawatan dengan Reamberin[®]

Dokter anda mungkin memiliki lebih banyak informasi tentang obat-obatan yang harus diperhatikan atau dihindari saat diberikan obat ini

3. Bagaimana cara penggunaan Reamberin[®] 1,5 % larutan untuk infus

- Berapa banyak dan berapa lama penggunaannya

Pada orang dewasa dan anak-anak Reamberin[®] harus diberikan secara intravena melalui infus berkelanjutan pada tingkat yang berbeda. Dosis harian untuk orang dewasa adalah 400 – 800 mL.

Dosis harian untuk anak-anak adalah 6 - 10 mL/kg berat badan, tidak lebih dari 400 mL.

Kecepatan infus, durasi dan dosis diperkirakan berdasarkan kondisi pasien dan akan diputuskan oleh dokter Anda.

Reamberin[®] akan diberikan oleh dokter Anda atau tenaga kesehatan lainnya, yang akan memonitor anda selama dan setelah pemberian.

- Jika anda lupa menggunakannya

REAMBERIN[®]
Solution for Infusion

ACTD – PART I.
ADMINSTRATIVE DATA

RMB-2025



b. Patient Information Leaflet (PIL)

Karena Reamberin[®] diberikan oleh dokter, tidak mungkin Anda lupa menggunakannya. Namun, jika Anda khawatir, bicarakan dengan dokter Anda.


- Jika anda menggunakan terlalu banyak (overdosis)
Tidak ada kasus overdosis dengan Reamberin[®] yang terdaftar atau dilaporkan. Karena pemanfaatan yang cepat pada organisme yang overdosis dengan Reamberin[®] tidak mungkin terjadi. Jangan menggunakan Reamberin[®] lebih dari dosis yang ditentukan.

4. Kemungkinan efek samping

Jika diberikan terlalu cepat, efek samping berikut dapat terjadi diklasifikasikan menurut frekuensi efek samping yang terjadi sebagai berikut:

- *sangat umum (frekuensi efek samping $\geq 1 / 10$);*
- *umum (frekuensi efek samping $\geq 1 / 100 - < 1/10$);*
- *agak jarang (frekuensi efek samping $\geq 1 / 1000 - < 1/100$);*
- *jarang (frekuensi efek samping $\geq 1 / 10000 - < 1/1000$);*
- *sangat jarang (frekuensi efek samping $< 1/10000$);*
- *tidak diketahui (frekuensi efek samping tidak dapat ditentukan berdasarkan data yang diperoleh).*

Sistem Organ	Frekuensi efek samping	Reaksi Obat yang Tidak Diinginkan
<u>Gangguan sistemik dan kelainan lokal pada tempat penyuntikan</u>	sangat jarang	hipertermia atau suhu tubuh yang tinggi, menggigil, berkeringat, lemah, iritasi lokal pada tempat injeksi, edema, hiperemia atau peningkatan jumlah darah di pembuluh suatu organ atau jaringan di tubuh, flebitis atau radang pembuluh darah;
<u>Gangguan kekebalan tubuh</u>	sangat jarang	alergi, angioedema atau pembengkakan di bawah kulit, syok anafilaksis;
<u>Gangguan jaringan kulit dan subkutan:</u>	sangat jarang	ruam alergi, biduran, gatal-gatal
<u>Gangguan pernapasan, organ dada dan kelainan mediastinum</u>	sangat jarang	dyspnea atau sesak napas, batuk kering;
<u>Gangguan jantung</u>	sangat jarang	takikardia, palpitasi, dyspnea atau sesak napas, nyeri dada;
<u>Gangguan vaskular:</u>	sangat jarang	hipotensi / hipertensi arteri, reaksi jangka pendek dalam

REAMBERIN[®] Solution for Infusion		
ACTD – PART I. ADMINSTRATIVE DATA	RMB-2025	 Polysan <small>Intelligent protection of health</small>
b. Patient Information Leaflet (PIL)		

		bentuk sensasi panas dan eritema tubuh bagian atas;
<u>Gangguan gastrointestinal:</u>	sangat jarang	mual, muntah, rasa logam di mulut, nyeri di bagian perut, diare;
<u>Gangguan sistem saraf</u>	sangat jarang	pusing, sakit kepala, kejang, tremor, parestesi atau kesemutan, agitasi, kecemasan.

Jika efek samping terjadi, laju infus harus diturunkan.

Beritahu dokter Anda, jika ada efek yang tidak diinginkan yang memburuk atau jika Anda perhatikan ada efek yang tidak diinginkan lainnya yang tidak disebutkan diatas.

Pelaporan efek samping

Jika Anda mengalami efek samping apapun, bicarakan dengan dokter Anda. Termasuk kemungkinan efek samping yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping secara langsung (lihat di bawah). Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

Indonesia	Tim Farmakovigilans PT PYRIDAM FARMA, Tbk. Email: pv.safety@pyfa.co.id
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5. Bagaimana cara penyimpanan Reamberin[®] 1,5 % larutan untuk infus

- Simpan pada suhu di bawah 30°C.
- Jangan menggunakan obat yang telah melewati batas kadaluwarsa.
- Jauhkan dari jangkauan anak-anak.
- Jika terjadi perubahan warna dan terjadi endapan, penggunaan obat tidak diperbolehkan.

6. Isi kemasan dan informasi lainnya

1 botol Reamberin[®] 400 mL mengandung:

Zat Aktif:

Meglumin sodium succinate 6,00 g

Diperoleh dengan mencampurkan:

Succinic Acid 2,112 g

Meglumine 3,490 g

Eksipien:

Sodium chloride 2,40 g

Potassium chloride 0,12 g

Magnesium chloride hexahydrate (sebagai anhidrat) 0,048 g

Sodium hydroxide 0,7152 g

REAMBERIN[®]
Solution for Infusion

ACTD – PART I.
ADMINSTRATIVE DATA

RMB-2025



b. Patient Information Leaflet (PIL)

Succinic acid
Water for injections

hingga pH 6,0 – 7,0
hingga 400 mL

Diproduksi oleh:

“Scientific Technological Pharmaceutical Firm “POLYSAN” Ltd (“STPF “POLYSAN” Ltd.)
Lit.A, Building 2, 72 Salova Street, Saint Petersburg, 192102, Russia
Telepon: +7 (812) 448-22-22

HARUS DENGAN RESEP DOKTER

Didaftarkan oleh:

PT. Pyridam Farma Tbk.
Sinarmas Land Plaza Sudirman, 12th Floor,
Jl. Jendral Sudirman Kav.21,
Kel. Karet, Kec. Setiabudi,
Kota Adm. Jakarta Selatan,
DKI Jakarta 12920, Indonesia

Nomor Registrasi: DKI2161600149A1