DivaLin
Leuprorelin acetate
Injection for SC or IM 3.75 mg

PRODUCT DESCRIPTION
Pharmaceutical form: sustained-release microcapsules, dispersing agent

Appearance
Macroscopic: White powder without discoloration or superficial foreign particles.
Microscopic: Microspheres

COMPOSITION
DivaLin 3.75 mg
1vial contains:
Leuprorelin acetate 3.75 mg, PLGA• 33.10 mg, mannitol
6.60 mg, gelatine 0.65 mg
*PLGA: copolymer of DL-lactatic/glycolic acid (75:25 mol %)
1 solvent ampoule contains:
Mannitol 75 mg, carboxymethylcelullose sodium 7.5 mg,
Polysorbate 80 1.5 mg, water for injection 1.5 ml

PHARMACOLOGICAL PROPERTIES
Leuprorelin acetate is a parenterally administrable synthetic nonapeptide, an analogue of the naturally occurring hypothalamic “releasing factor” GnRH, which controls the release of the gonadotropic hormones LH (lutenizing hormones) and FSH (follicle-simulating hormones) from the anterior lobe of the hypophysis.
In contrast to physiological GnRH, which is released from the hypothalamus in pulsatile fashion leuprorelin acetate, which is also designated as a GnRH against, continuously blocks the GnRH receptors of the hypophysis on regular therapeutic administration and causes their desensitization (“down-regulation"). As a result after an initial short-term stimulation a reversible hypophyseal suppression of gonadotropin release occurs and therewith a decrease in the testosterone or oestradiol (E2) secretion.

*Prostate carcinoma*
A lowering of the testosterone level occurs and therewith an influencing of the growth of the carcinomatously altered prostate tissue, which is normally stimulated by dihydrotestosterone-formed by reduction of testosterone in the prostate cells.
Because of the initial transient increase in the testosterone level, with symptomatic worsening of the clinical picture in isolated cases, an additional administration of antiandrogens is to be considered. Long-term therapy with leuprorelin acetate in comparison causes a lowering of the LH and FSH levels in all patients; In man androgen levels such as are presents after bilateral orchiectomy are achieved. These changes usually occur two to three weeks after the start of therapy and are manifest over the entire treatment period. For this reason, the hormone sensitivity of a prostate carcinoma and the possible therapeutic value of an orchiectomy can be checked using DivaLin. If desired, the orchiectomy can be replaced by the monthly administration of DivaLin.
Hitherto, it has been possible to maintain castration levels of testosterone over the course of five years after continuous administration of leuprorelin acetate.

*Endometriosis*
Oestrogens stimulate the growth of endometrial tissue. With DivaLin after an initial short-term E2 rise, a subsequent decrease in the values to the postmenopausal range occurs (E2 < 30 pg/ml).
This hypo-oestrogenic state is reliable maintained during the entire period of therapy and leads to atrophic changes in the uterine and ectopic endometrial tissue.
This leads in the course of treatment to the disappearance of endometriosis foci, prevents the formation of new endometriosis implants and reduces adhesions, which finally leads to a decline in pain and typical symptoms.
The menstrual period commences again on average 3 months after the end of the recommended 6 months therapy.

**PHARMACOKINETIC**
After injection of the DivaLin suspension, the active agent leuprorelin acetate is released continuously from the copolymer, consisting of glycolic acid and lactic acid in the ratio 1:3, over the period of one month. The copolymer is absorbed here like surgical suture material. Within an hour, after a single administration of 3.75 mg of leuprorelin acetate s.c., serum levels of 13 ng/mL are measured. Detectable levels in the serum are present up to 35 days after the last administration. The distribution volume of leuprorelin acetate is 36 L and the total clearance is 139.6 mL/min.
In patients having restricted kidney function, in some cases higher serum levels of leuprorelin acetate were measured after administration of DivaLin, but decreased values in patients having restricted liver function. Clinically, this observation, however, appears to be without relevance.

INDICATIONS
Treatment of prostatic cancer with metastases, treatment of endometriosis at genital and extra genital localization (from stage I to stage IV, it's limited to women >18 years).
It is not recommended to start second therapy with leuprolide or GnRH analogue.

**Mode of Administration**
Using a sterile syringe, introduce 1 ml of solvent from the enclosed ampoule into the vial. With gentle swirling, prepare a ready to use homogeneous milky suspension and use immediately.
Discard the residue which is not needed.
*Introductions for use:*
1. Check that the entire contents of the ampoule of solvent are in the body of the ampule. Apply pressure until the neck of the ampoule breaks.

2. Using the needle and syringe provided with the kit, extract 1 ml of solvent. Discard the remainder.

3. Remove the plastic top from the ampoule vial and inject solvent into the vial.

4. Shake the ampoule vial to obtain a uniform suspension of milky appearance.

5. Extract the entire contents of the vial, tilt the vial slightly and place the bevel of the needle at its base. Do not invert the ampoule vial.

6. Disinfect the skin where the injection is to be administered, and inject the contents of the syringe using the second needle provided with the kit.

**DOSAGE**

*In Prostate Carcinoma*

The administration of DivaLin must only be carried out under the supervision of a physician who is experienced in tumour therapy. The usual recommended dose is 3.75 mg administered as a single subcutaneous or i.m. injection every month. DivaLin therapy should not be discontinued when remission or improvement occurs, as with other drugs administered chronically by injection, the injection site should be varied periodically.

As a rule, the therapy of advanced, hormone-dependent prostate carcinoma is a long-term treatment.

*In endometriosis:*

The recommended dose is 3.75 mg administered as a single subcutaneous or i.m injection every month for a period of 6 month only, treatment should be initiated during the first 5 days of the menstrual cycle. In women receiving GnRH analogues for the treatment of Endometriosis, the addition of hormone replacement therapy (HRT as oestrogen and progestogen) has been shown to reduce bone mineral density loss and vasomotor symptoms. Therefore if appropriate, HRT should be co-administered with DivaLin taking into account the risks and benefits of each treatment.

**CONTRAINDICATIONS**

- Hypersensitivity to leuprorelin or other GnRH analogues, polyglycolic acid, polylatic acid or another constituent of the preparation.
- Intra-arterial injection.
- In the case of proven hormone independence of prostate carcinoma. DivaLin should not be employed. After surgical castration, DivaLin causes no further fall in the testosterone level.
- Pregnancy and lactation.
- Unclarified vaginal haemorrhages.
- Premalignant or malignant changes of the endometrium (In endometrial ablation/endometrial reaction).
- Vaginal bleedings of undetermined origin

Particular caution is demanded in female patients with additional risk factor with regard to osteoporosis (chronic alcohol and nicotine abuse, increased familial occurrence of osteoporotic symptoms. long-term therapy with anticonvulsants and corticoids).

**UNDESIRABLE EFFECTS**

Initially, a short-term increase in the serum testosterone or serum oestradial level regularly occurs, in women, this leads in most cases to bleeding with subsequent amenorrhea, and ovarian cysts possibly occur.

In addition, in patients with prostate carcinoma this can lead to a temporary intensification of certain disease symptoms (occurrence of or increase in bone pain, hypercalcemia, urinary tract abstraction and it sequelae, bone marrow compression, muscle weakness in the legs. lymphoedemal). This increase in the symptoms usually spontaneously diminishes without DivaLin having to be discontinued.

For the initial phase of the treatment of prostate carcinoma, the additional administration of a suitable antiandrogen should be considered in order thus to lessen the possible secondary symptoms of the initial testosterone increase and the worsening of the clinical symptomatology.

As a result of the withdrawal of the sex hormones, the following side effect can occur; hot flashes, increased perspiration, decrease in libido and potency, reduction in the size of the testes, decrease or increase in size of breast, gynaecomasty, mood swings, depressive moods or possibly intensification of a preexisting symptomatology, change in the hairiness of the head or body (decrease increase), dry vagina, vaginitis, discharge, smear bleeding, bladder symptoms, acne, dry skin, decrease in the bone mass, increase in enzymes such as LDH, AL(SGPT),AST (SGOT), YGT and of alkaline phosphate in the blood.

In addition, the following can occur; headaches (in rare cases migraine-like), sleep disturbances, nervousness, tiredness, dizziness, memory disorders, vertigo, nausea, vomiting, loss of appetite, weight increase or decrease, diarrhea, constipation, abdominal symptoms, paraesthesias/feeling of numbness, visual disturbances, respiratory symptoms, feeling of weakness, back, limb, joint and muscle pain, circulatory symptoms (increase or decrease in blood pressure, palpitations, syncopes), occasionally water retention in the face or in the legs.

In isolated cases, erythema or local reactions can occur at the injection site. In rare cases, general allergic reactions (fever, itching, and exanthema) are also possible.

As with all parenterally administered peptide compounds, the occurrence of anaphylaxis cannot be completely excluded.

**Special Warnings for Safe Use**

*In Prostate Carcinoma*

Patient with known depression or existing depressive moods should be monitored carefully under therapy. The therapeutic success should be checked regularly (but in particular in the case of signs of progression despite adequate therapy) by means of clinical examinations (rectal palpation of the prostate, sonography, skeletal scintigraphy for the checking of reactive bone changes, computer tomography) and by monitoring of the phosphatases or of prostate specific antigen (PSA) and of serum testosterone.

The reaction to the therapy with DivaLin can be checked by measurement of the serum levels of testosterone, acid phosphatase and P5A (prostate-specific antigen). Thus, the testosterone level initially increase at the start of treatment and then falls again during the course of a period of two weeks. After two to four weeks, testosterone levels such as are observed after a bilateral orchiectomy are reached, and are maintained over the entire treatment period. An increase in add phosphatase levels can take place in the initial phase of the therapy and is of temporary nature. Usually, after a few weeks normal values or approximately normal values are reached again. Patients having threatening neurological complications, spinal column metastases and urinary tract obstruction should be under continuous monitoring. If possible in-patients monitoring, during the first weeks of treatment.

*In endometriosis*

Patients having known depression or existing depressive moods should be monitored carefully under therapy. Oral contraceptives (contraceptive pills) are to be discontinued before the start of treatment with DivaLin. For safely, in the first month of the treatment other measures for the prevention of a pregnancy should be carried out, e.g. mechanical contraceptive measures such as condoms.

The first injection should be carried out approximately on the third day of menstruation in order largely to exclude on existing pregnancy. In the case of doubt, carrying out a pregnancy test is recommended. In the course of the therapy a lowering of the sex hormone levels occurs, such that a later occurrence of a pregnancy is not be excepted. DivaLin should be administered at monthly intervals which are as exact as possible. As an exception, an alteration in the injection appointment by few days does not adversely affect the therapeutic success, but increase the risk of breakthrough bleeding.
Result on the fertility rate after the end of therapy from controlled studies are not available. In long-term observations in open studies, pregnancies occurred in previously infertile women.
In very rare cases, on treatment with GnRH analogues an irreversible menopause can occur. This has not been observed up to now with DivaLin.
In the treatment of endometriosis, care should be taken that in the therapy of a mild clinical picture a careful benefit-risk assessment is carried out an account of the later high recurrence rates. It should, however, also be taken into consideration that the recurrence rate is further increased, the further advanced the stage of endometriosis is at the time of therapy.
In severe forms of endometriosis, following the therapy with DivaLin a possible surgical after treatment should be taken into consideration.

In the menopause, the bone density decreases (can lead to osteoporosis). A decrease in the bone density can also occur after several months use in the case of medicinally induced oestrogen deficit, e.g. with DivaLin. After discontinuation of therapy, the bone demineralization can remit within 3 to 6 months depending on the location. In some of patients, this degeneration can lost beyond this period.
Patients having high blood pressure should be monitored particularly carefully.

Should not be used in women who are breast-feeding.

A worsening of sign and/or symptoms of hormone-dependent disease (e.g. endometries, prostatic carcinoma) has occasionally occurred during the first 1-2 weeks of DivaLin therapy (secondary to DivaLin induced stimulation release of gonadotropin and result ovarians and testicular steroidogenesis, and those sign and of symptoms will be subside if the therapy is discontinued). Because safety in women has not been established beyond 6 months and because of concerns about potential long-term effect on bone density DivaLin therapy extending beyond this period of additional courses of therapy with this or another GnRH analogue currently are not recommended in women.
Patient should not use this drug if they have undiagnosed abnormal vaginal bleeding, or and allergic to any of the ingredients of this drug.
A repeat of an anaphylactic reaction to synthetic GnH (Gonadorelin HCl) has been reported in the medical literature.

**INTERACTION WITH OTHER AGENTS**
*Pregnancy and lactation*
DivaLin is contraindicated during pregnancy and lactation.

*Effects on fitness to drive and to operate machine are unknown.*

**OVERDOSE**
Intoxication symptoms have hitherto not been observed. Even in the case of administration of dosed of up to 20 mg of leuprorelin acetate per day over the course of two years, which were used in the first clinical studies, it was not possible to find any other side effects or new side effects which differ from those after daily administration of 1 mg or monthly administration of 3.75 mg.

**ON DOCTOR'S PRESCRIPTION ONLY**
**HARUS DENGAN RESEP DOKTER**

**PHARMACEUTICAL PARTICULARS**
List of excipients:
Gelatin, Mannitol, Carboxymethylcellulose Sodium, Polysorbate 80, Copolymer of DL Lactic/Glycolic Acid, Water for Injection

**PRESENTATION**
DivaLin 3.75 rng x 1vialwith 1 solvent ampoule, 1disposable syringe and 2 22 G1 ½ needles.

**Reg. No.: DKI1811300744A1**

**Storage Conditions:**
Do not store above 25"C.
Keep the container in the outer carton. Do not freeze.

Manufactured by:
Eriochem S.A., Paraná, Argentina

Imported and Marketed by:
Darya-Varia
LABORATORIA

Jakarta, Indonesia

MST-PR-4022-04

210 mm

Material : Paper 50gr/m2
Color: Pantone Black
Size : 210 x 420 mm

Frutiger65-Bold_16.0 pt
Frutiger65-Bold_12.8 pt

# DivaLin®

## Leuprorelin acetate 3.75 mg
## Mikrokapsul lepas lambat, agen pelarut

**INFORMASI UNTUK PASIEN**
Leuprorelin asetat dapat digunakan untuk beberapa masalah terkait kesehatan, antara lain:
- Kanker prostat
- Nyeri karena endometriosis

Leuprorelin asetat merupakan hormon alamiah yang dikeluarkan oleh kelenjar hipotalamus.
Ketika diberikan secara rutin pada laki-laki dewasa atau anak laki-laki, leuprorelin asetat menurunkan kadar testosterone. Penurunan kadar testosterone dalam tubuh adalah cara untuk mengatasi kanker prostat.
Ketika diberikan secara rutin pada perempuan dewasa atau anak perempuan, leuprorelin asetat akan menurunkan kadar estrogen. Penurunan kadar estrogen dalam tubuh adalah cara untuk mengatasi endometriosis.

**SEBELUM MENGKONSUMSI LEUPRORELIN ASETAT**
Ketika memutuskan menggunakan obat ini, risiko penggunaan obat ini harus dipertimbangkan baik buruknya. Keputusan ini harus diambil bersama dengan dokter. Untuk leuprorelin asetat, beberapa hal yang harus dipertimbangkan antara lain:
**Alergi:** beritahu dokter Anda jika Anda memiliki alergi terhdap leuprorelin asetat, buserelin, gonadorelin, histrelin atau nafarelin.
**Kehamilan:** beritahu dokter Anda jika Anda merencanakan kehamilan.
Untuk laki-laki: leuprorelin asetat dapat menyebabkan steril sementara. Pastikan Anda telah berdiskusi dengan dokter Anda sebelum mengkonsumsi obat ini.
Untuk perempuan: ada kemungkinan leuprorelin asetat dapat menyebabkan kecacatan jika dikonsumsi setelah Anda hamil. Dapat juga terjadi keguguran jika dikonsumsi saat hamil.

**Hentikan penggunaan obat ini dan informasikan ke dokter Anda segera setelah Anda pikir Anda hamil.**

**Menyusui:** tidak diketahui apakah leuprorelin asetat masuk melalui ASI. Namun demikian, penggunaan leuprorelin asetat tidak direkomendasikan selama menyusui karena dapat menyebabkan hal yang tak diinginkan.
**Usia lanjut:** banyak obat-obatan yang tidak dilakukan penelitian pada orang tua. Oleh karena itu, tidak diketahui apakah mekanisme kerja obat pada orang tua sama dengan orang usia lebih muda. Meskipun tidak ada informasi spesifik tentang penggunaan leuprorelin asetat pada orang tua, tidak diharapkan menyebabkan efek samping yang berbeda atau masalah pada orang yang lebih tua daripada pada orang dewasa muda.
**Obat lain:** meskipun obat-obatan tertentu tidak boleh digunakan bersama-sama, namun dalam kasus lain dua obat dapat digunakan bersama-sama bahkan jika interaksi mungkin terjadi. Dalam hal ini, Dokter Anda mungkin akan merubah dosis, atau tindakan pencegahan lain mungkin diperlukan. Katakan kepada dokter Anda jika Anda minum obat resep atau obat bebas lainnya.
**Masalah medis lainnya:** adanya masalah medis lainnya dapat mempengaruhi penggunaan leuprorelin asetat. Pastikan Anda memberi tahu dokter Anda jika Anda memiliki masalah medis lainnya, terutama:
- Perubahan pada perdarahan vagina dari penyebab yang tidak diketahui (untuk digunakan untuk endometriosis atau anemia karena tumor rahim): Leuprorelin asetat dapat menunda diagnosis atau menyebabkan kondisi memburuk. Sebelum leuprorelin asetat digunakan, tentukan terlebih dahulu sebab perdarahan.
- Kondisi yang memperbesar kemungkinan terjadinya penipisan tulang.
- Osteoporosis, riwayat osteoporosis atau riwayat keluarga: penting bagi dokter untuk mengetahui jika Anda memiliki faktor risiko terjadi osteoporosis. Beberapa hal dapat meningkatkan risiko terjadinya osteoporosis termasuk merokok, alkohol, dan adanya riwayat osteoporosis dalam keluarga atau yang mudah terjadi patah tulang. Beberapa obat-obatan seperti kortikosteroid (seperti kortison) atau antikonvulsan (obat kejang) juga dapat menyebabkan penipisan tulang jika digunakan dalam waktu lama.
- Masalah saraf dapat terjadi karena lesi tulang di tulang belakang (untuk kanker prostat).
- Masalah dalam buang air kecil (untuk digunakan untuk kanker prostat): kondisi bisa memburuk untuk waktu yang singkat setelah perawatan Leuprorelin asetat dimulai.

**PENGGUNAAN YANG TEPAT DARI LEUPRORELIN ASETAT**
**Baca instruksi ini dengan seksama.**
Gunakan obat ini hanya seperti yang diarahkan oleh dokter Anda. Jangan gunakan lebih banyak atau lebih sedikit, dan jangan menggunakannya lebih sering daripada yang diperintahkan dokter Anda. Jumlah obat yang tepat untuk Anda diperlukan untuk mendapat hasil optimal. Penggunaan berlebihan dapat meningkatkan efek samping, dan penggunaan terlalu sedikit tidak memperbaiki kondisi Anda.

**Dosis yang terlewatkan:** Jika Anda menggunakan obat ini sebulan sekali dan Anda melewatkan dosis, dapatkan obat ini sesegera mungkin, dan kembali ke jadwal pemberian dosis rutin Anda.

**Bagaimana menyimpan obat ini:**
- Jauhkan dari jangkauan anak-anak.
- Jauhkan dari panas dan cahaya langsung.
- Jangan disimpan di *freezer*.
- Jangan menyimpan obat yang sudah kadaluwarsa atau yang tidak Anda gunakan lagi. Pastikan bahwa setiap obat yang dibuang berada di luar jangkauan anak-anak.

**TINDAKAN PENCEGAHAN SAAT MENGGUNAKAN LEUPRORELIN ASETAT**
Sangat penting dokter Anda memeriksa kemajuan Anda pada kunjungan rutin untuk memastikan bahwa obat ini berfungsi dengan baik dan untuk memeriksa efek yang tidak diinginkan.
- Untuk pasien yang menerima leuprorelin asetat untuk endometriosis:
  Selama waktu Anda menerima leuprorelin asetat, periode menstruasi Anda mungkin tidak teratur atau Anda tidak menstruasi sama sekali. Hal ini dapat terjadi saat menggunakan obat ini. Jika menstruasi yang teratur tidak terjadi dalam 60 hingga 90 hari setelah Anda berhenti menerima obat ini, tanyakan kepada dokter Anda.
  Selama waktu Anda menerima leuprorelin asetat, Anda harus menggunakan metode pengendalian kelahiran (KB) yang tidak mengandung hormon. Jika Anda memiliki pertanyaan tentang hal ini, tanyakan kepada dokter Anda.
  Jika Anda curiga Anda mungkin telah hamil, berhenti menggunakan obat ini dan periksa ke dokter Anda. Penggunaan leuprorelin asetat selama kehamilan dapat menyebabkan cacat lahir atau keguguran.

**EFEK SAMPING PENGGUNAAN LEUPRORELIN ASETAT**
Seiring dengan efek yang dibutuhkan, obat ini dapat menyebabkan beberapa efek yang tidak diinginkan. Meskipun tidak semua efek samping ini dapat terjadi, namun jika efek samping ini terjadi, maka mungkin memerlukan perhatian medis.

**Dapatkan bantuan darurat segera jika salah satu dari efek samping berikut terjadi:**
**Untuk dewasa:**
Kurang umum terjadi: detak jantung cepat atau tidak teratur
Jarang terjadi: tulang, otot, atau nyeri sendi; perubahan warna kulit wajah; pingsan; napas cepat atau tidak teratur; mati rasa atau kesemutan tangan atau kaki; bengkak atau pembengkakan kelopak mata atau di sekitar mata; sesak napas; ruam kulit, gatal-gatal, dan/atau gatal; penurunan tekanan darah tiba-tiba yang parah dan kolaps; sesak di dada atau mengi; pernapasan bermasalah

**Untuk laki-laki dewasa:**
Jarang terjadi: nyeri di dada; nyeri di pangkal paha atau tungkai (terutama di betis)

**Periksa ke dokter Anda segera mungkin jika terjadi efek samping berikut ini:**
**Untuk perempuan dewasa:**
Jarang terjadi: kecemasan, suara yang lebih berat; peningkatan pertumbuhan rambut; depresi mental; perubahan suasana hati; kegugupan

**Untuk anak-anak**
Jarang terjadi: nyeri tubuh, rasa terbakar, gatal, kemerahan atau pembengkakan pada tempat suntikan; *rash* (kemerahan) pada kulit.
**Untuk anak perempuan, terjadi pada minggu-minggu awal:**
Jarang terjadi: perdarahan vagina; keputihan

Efek samping lain yang dapat terjadi, biasanya tidak membutuhkan perhatian medis. Efek samping ini mungkin hilang selama perawatan saat tubuh Anda menyesuaikan dengan obat. Namun, periksa dengan dokter Anda jika ada efek samping berikut ini yang berlanjut atau mengganggu:

**Untuk dewasa:**
Lebih sering terjadi: berkeringat tiba-tiba dan merasa panas (disebut juga *hot flashes*).
Kurang umum terjadi: penglihatan kabur, rasa terbakar, gatal, kemerahan, atau pembengkakan di tempat suntikan, penurunan libido, pusing, sakit kepala, mual atau muntah, pembengkakan kaki atau tungkai bawah, pembengkakan dan nyeri payudara; kesulitan tidur dan peningkatan berat badan.

**Untuk perempuan dewasa:**
Lebih sering terjadi: perdarahan vagina yang ringan dan tidak teratur; berhenti menstruasi
Kurang umum terjadi: rasa terbakar, kering, atau gatal pada vagina; nyeri panggul.

**Untuk laki-laki dewasa:**
Kurang umum terjadi: nyeri tulang, konstipasi, mengecilnya testis, tidak dapat atau tak dapat mempertahankan ereksi.
Efek samping lain mungkin tidak tertulis di atas dan dapat terjadi pada pasien. Jika Anda mengalami efek samping lain, informasikan ke dokter Anda.

**HARUS DENGAN RESEP DOKTER**

**KEMASAN**
DAN INFORMASI LAINNYA

**Kandungan DivaLin Mikrokapsul lepas lambat, agen pelarut**
Zat aktif Divalin adalah mengandung leuprorelin acetate
**Bahan lainnya**
Gelatin, Mannitol, Natrium Karboksimetilselulosa, Polisorbat 80, Kopolimer DL Asam Laktat/Glikolat, Air untuk Injeksi
**Tampilan DivaLin dan kemasannya**

DivaLin 3,75 mg x 1 vial dengan 1 ampul, 1 *disposable syringe* dan 2 jarum 22 G1 ½

Reg No. DKI1811300744A1

Kondisi penyimpanan: Jangan disimpan pada suhu diatas 25°C.
Simpan wadah pada karton luar. Jangan dibekukan.

Diproduksi oleh:
**Eriochem S.A., Parana, Argentina**

Diimpor dan Dipasarkan oleh:

Darya-Varia LABORATORIA

**Jakarta, Indonesia**

MST-PR-4218-01

420 mm

DISETUJUI OLEH BPOM : 22/04/2024

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