

ARTWORK DESIGN STANDARD FOLDING BOX



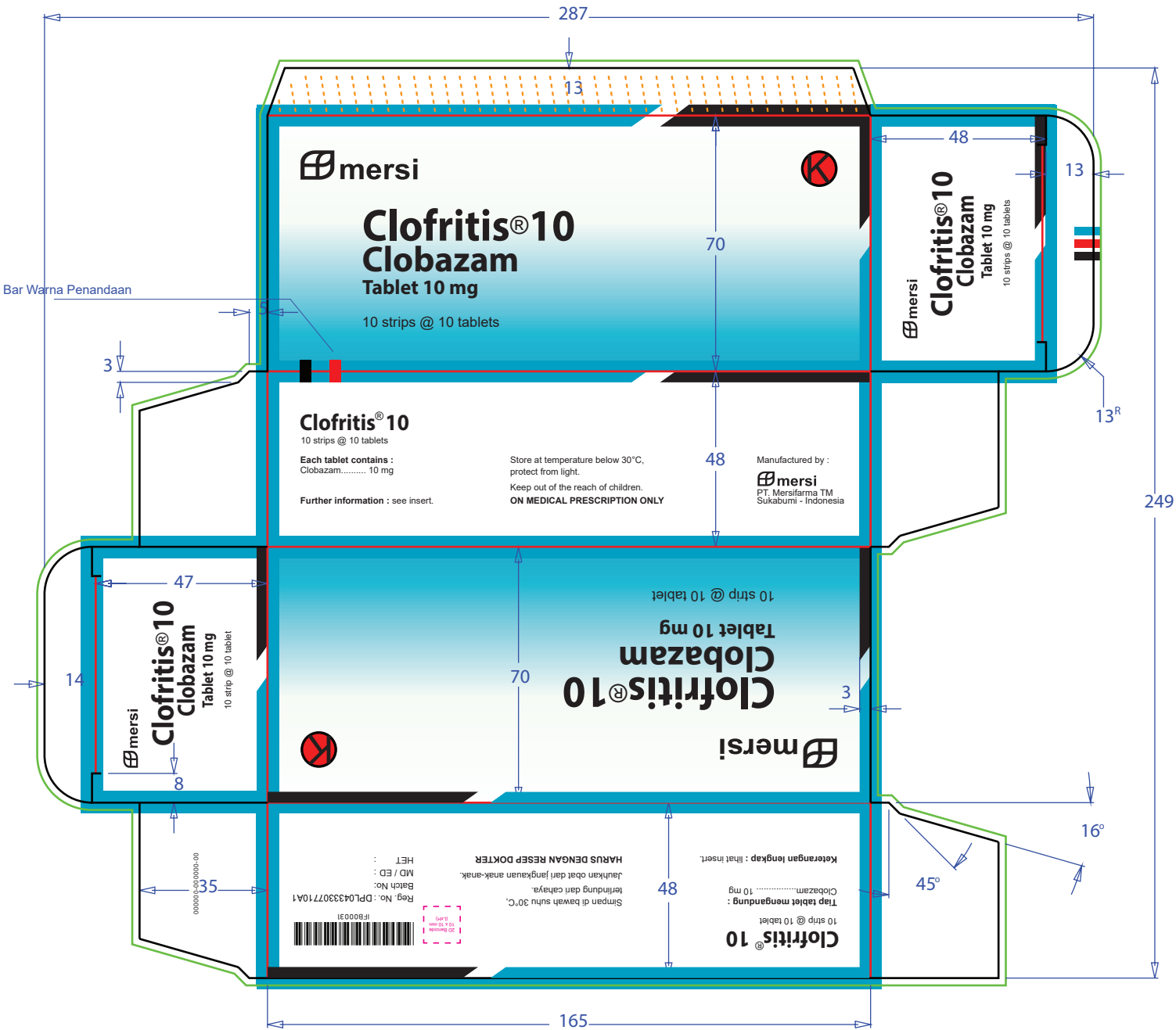
PT. MERSIFARMA TIRMAKU MERCUSANA  
DEPARTEMEN DESIGN & PACKAGING

Date of use: 20/06/2021  
(DD-MM-YYYY)

|                                               |                        |                       |                                                                                    |
|-----------------------------------------------|------------------------|-----------------------|------------------------------------------------------------------------------------|
| <b>CLOFRITIS 10</b>                           |                        |                       |  |
| <b>Dimension (L x W x H) 165 x 48 x 70 mm</b> |                        |                       |                                                                                    |
| Material                                      | Packsize/Primary       | Primary               | No. Reg                                                                            |
| Carton Duplex 270g                            | 10 strips @ 10 tablets | MST/ PE15/ AL20/ PE30 | DPL0433307710A1                                                                    |

| Front / Rear Panel |                     |              | Left / Right Side Panel |              | Top Closure Panel |                     |              |
|--------------------|---------------------|--------------|-------------------------|--------------|-------------------|---------------------|--------------|
| Type Font          |                     |              | Type Font               |              | Type Font         |                     |              |
| Product Name       | Active Ingredient   | Another Font | Product Name            | Another Font | Product Name      | Active Ingredient   | Another Font |
| Myriad Pro, Bold   | Myriad Pro, Regular | Arial        | Myriad Pro, Bold        | Arial        | Myriad Pro, Bold  | Myriad Pro, Regular | Arial        |
| 35pt               | 28pt                | 11pt         | 18pt                    | 7pt          | 24pt              | 19.2pt              | 7pt          |

SKETCHES



Not at scale - Size in mm

|                                                                                     |               |                                                                                     |                                                                                      |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                                                    |
|-------------------------------------------------------------------------------------|---------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
|  | Cut           |  |  |  |  |  |  |  | Material Code<br><br>IFB00031 |
|  | Crease        | Ø10mm                                                                               | 32 x 8mm (LxH)                                                                       | 16 x 4mm (LxH)                                                                        | Gradient TC 3614 to White                                                             | LIGHT BLUE TC 3614                                                                    | RED TC 1315                                                                           | Black                                                                                 |                                                                                                                    |
|  | Outside Bleed | Finishing : Full Varnish Type Water Base                                            |                                                                                      |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                                                    |
|  | Glue Flap     |                                                                                     |                                                                                      |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                       |                                                                                                                    |



ARTWORK DESIGN STANDARD POLYCEL



PT. MERSIFARMA TIRMAKU MERCUSANA  
DEPARTEMEN DESIGN & PACKAGING

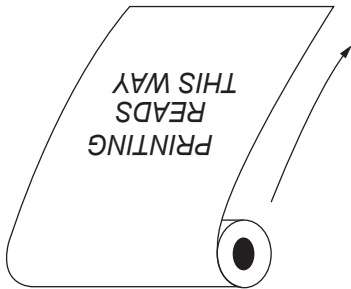
Date of use: 11/11/2024  
(DD-MM-YYYY)

|                           |              |
|---------------------------|--------------|
| CLOFRITIS 10              |              |
| Size (L x W) 500 x 310 mm |              |
| Material                  | No. Reg      |
| MST/PE15/AL12/PE30        | XXXXXXXXXXXX |

| Front / Rear Panel |                   |              |
|--------------------|-------------------|--------------|
| Type Font          |                   |              |
| Product Name       | Active Ingredient | Another Font |
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| 9pt                | 7.2pt             | 6pt          |

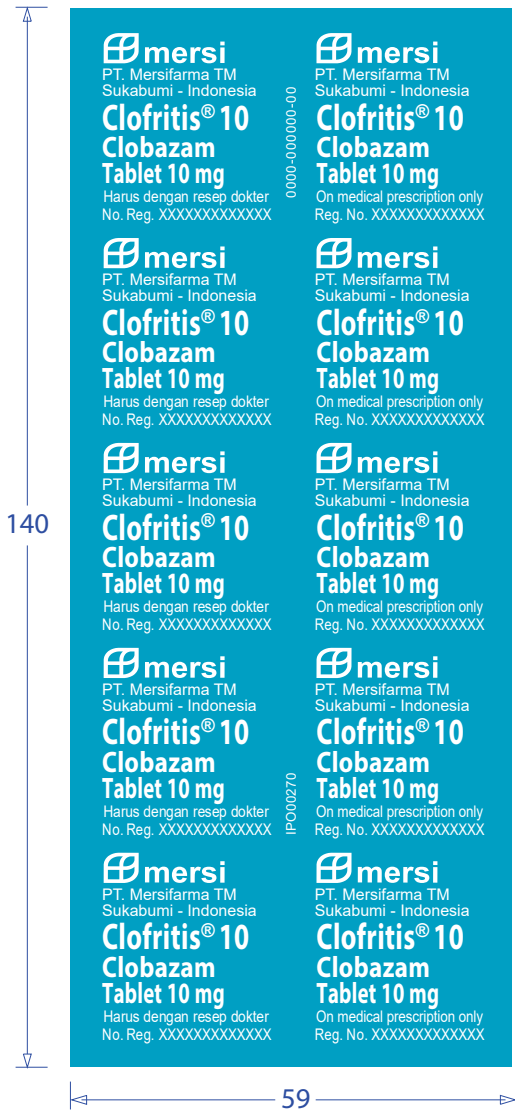
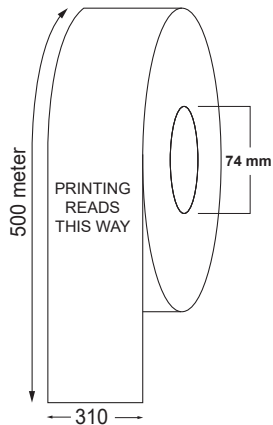
SKETCHES

PRINTING LAYOUT



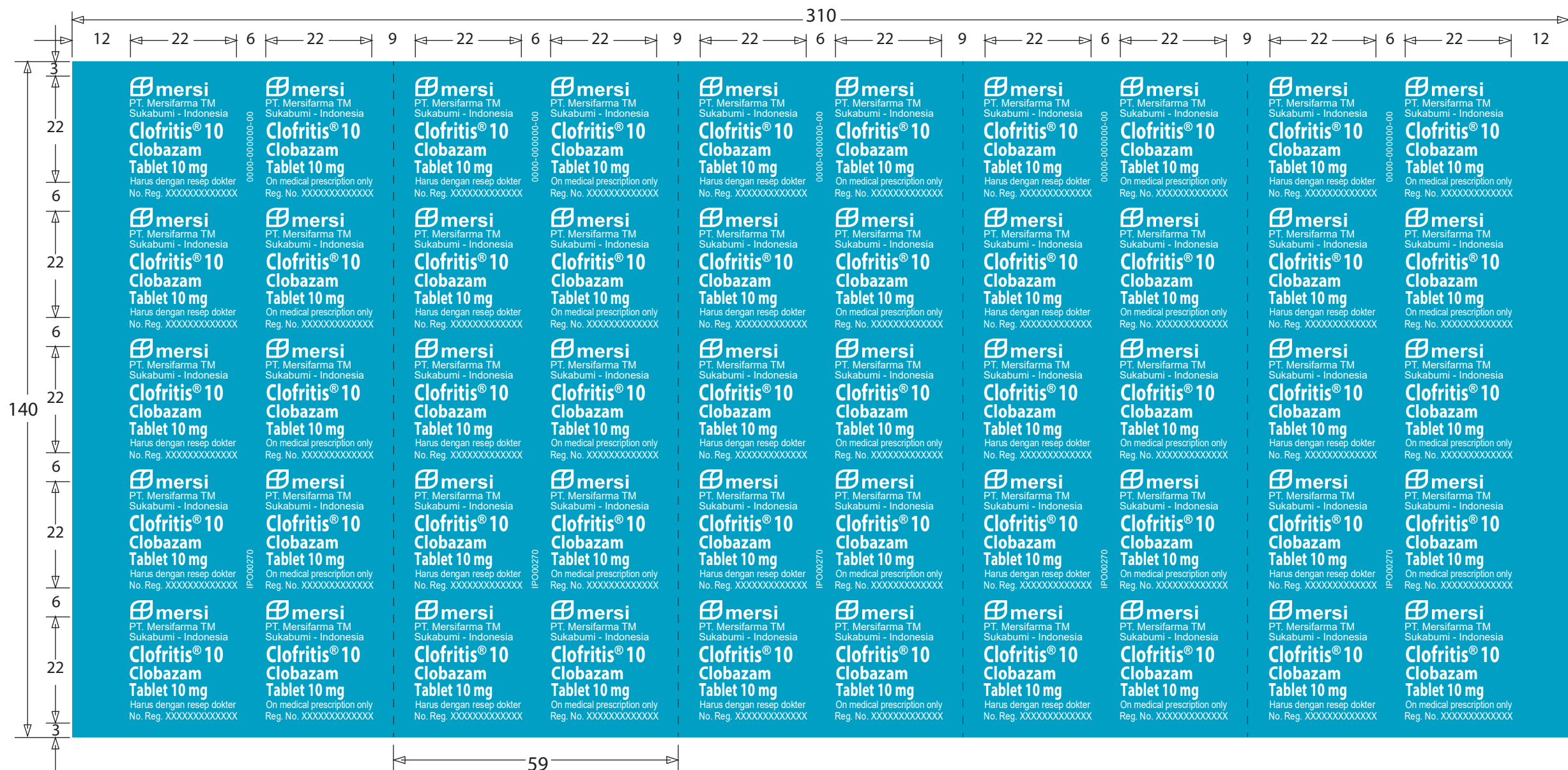
Bottom of design leading into machine

ROLL PRINTED POLYCEL

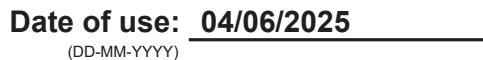


Not at scale - Size in mm

|                |            |                    |               |
|----------------|------------|--------------------|---------------|
|                |            |                    | Material Code |
| 16 x 4mm (LxH) | TEXT WHITE | LIGHT BLUE TC 3614 | IPO00270      |



|                                  |
|----------------------------------|
| <b>CLOFRITIS 10</b>              |
| <b>Size (L x W) 100 x 319 mm</b> |



| Front / Back     |                              |
|------------------|------------------------------|
| Type Font        |                              |
| Product Name     | Another Font                 |
| Myriad Pro, Bold | Myriad Pro<br>Regular / Bold |
| 10pt             | 6pt                          |

**Note:**

**Clofritis®10**  
Tablet 10 mg

**DRUG DESCRIPTION**  
Concave tablet with white color tablet, diameter 7 mm, upper initial mf, lower initial blank.

**COMPOSITION**  
Each Clofritis 10 tablets contains Clofazimine ..... 10 mg

**EXCIPIENTS**  
Microcrystalline cellulose pH-102, Lactose monohydrate, Magnesium stearate, Talc, Sodium lauryl sulfate.

**ACTIONS**  
Antioxylic and psychosomatic agent.

**INDICATIONS**  
Anxiety and psychoneurotic states which may produce symptoms of anxiety.

**POSOLOGY AND METHOD OF ADMINISTRATION**  
**Posology**  
- Adults: 20 mg daily in divided doses, the doses of up to 30 mg daily if needed. In the severe case the dose should be increased to 60 mg daily.  
- Children > 3 years: 5-10 mg daily in divided doses.  
- Elderly: 10 - 15 mg daily in divided doses.  
**Method of Administration**  
The drug is given orally.

**CONTRAINDICATIONS**  
- Hypersensitivity to Clozabam or any of the excipients.  
- History of drug dependence.  
- Use in pregnancy and lactation: Clozabam should not be used in the 1<sup>st</sup> trimester of pregnancy and in the later stages, only if there are compelling indication for its use.  
- Clozabam should not be taken by nursing mothers, since it passes into the breast milk. If there are compelling indications for its use, breastfeeding should be stopped.  
- In patients with myasthenia gravis (risk of aggravation of muscle weakness).  
- In patients with severe respiratory insufficiency (risk of deterioration).  
- In patients with sleep apnoea syndrome (risk of deterioration).  
- In patients with severe hepatic insufficiencies (risk of precipitation of encephalopathy).

**SIDE EFFECTS**  
- Dryness of the mouth, constipation, loss of appetite, nausea, dizziness, or a fine tremor of the fingers.  
- Treatment with Clozabam should be discontinued if the paradoxical reactions occur eg. restlessness, irritability, acute agitation states, anxiety, suicidal tendencies, frequent muscle spasms.  
- Ataxia, drowsiness, confusion, and headaches.  
- Cutaneous reactions, eg. Eruptions or urticaria.  
- Impairment of respiratory function may be manifested in certain disease of the respiratory passages (eg. bronchial asthma) and in patients with brain damage.  
- After prolonged use of Benzodiazepines, impairment of consciousness, sometimes combined with respiratory disorders, has been reported in very rare cases.  
- Especially in patients receiving high doses or long-term treatment, there may be reversible abnormalities, eg. slowing or indistinctness of speech (disorders of articulation), lack of confidence in walking and other motor functions, visual disorders (double vision, nystagmus), weight gain or loss of libido.  
- Tolerance physical and/or psychic may develop especially during prolonged use.  
- Discontinuation of the therapy may result in withdrawal or rebound phenomenon. Abuse of Benzodiazepines has been reported.  
- When used as an adjunct in the treatment of epilepsy, this preparation may in rare cases cause restlessness and muscle weakness.  
- As with other Benzodiazepines, the therapeutic benefit must be balance against the risk of habituation and dependence during prolonged use.

**WARNINGS AND PRECAUTIONS**  
- Special caution is necessary if Clozabam is to be administered to patients with serious pathological muscle weakness (myasthenia gravis), unsteadiness of movement and gait due to disease of the spinal cord and cerebellum (spinal or cerebellar ataxia), and in case of acute poisoning with alcohol, hypnotics, analgesics, neuroleptic agents, antidepressants or Lithium, in patients with serious liver damage (eg. cholestatic jaundice) and in patients with transient cessation of respiration in sleep (sleep apnoea syndrome). Monitoring of respiratory functions is necessary in patients with severe acute respiratory impairment (respiratory failure).  
- Clozabam contains a Benzodiazepine derivate. Benzodiazepine are drugs for the treatment of certain disorders which are associated with restlessness and anxiety states, inner tension, or insomnia. When using Benzodiazepine, there is a risk of developing or promoting dependence. To minimize this risk, the patients is advised to follow doctor's instruction.  
- When Benzodiazepines have been taken for a maximum of 4 weeks, the doctor should decide whether the treatment is to be continued. An uninterrupted, prolonged period of administration should be avoided, as it may lead to dependence.  
- When Benzodiazepines are discontinued after prolonged use, restlessness, anxiety states, and insomnia may occur, often after a delay of several days. These withdrawal symptoms usually disappear after 2 - 3 weeks.  
- A doctor must be consulted if the patients has suffered or is still suffering from alcohol, drug dependence, or heavy drug addiction. If this is the case. The patients must not take Benzodiazepines except in rare situations determined only by the doctor.  
- Under experimental conditions, impairment of alertness has been observed to be less pronounced after therapeutic doses of Clozabam than after other Benzodiazepine. Nevertheless, even when used as directed, Clozabam may alter reactively to such an extent as to impair driving performance or the ability to operate machinery, especially when it is taken in conjunction with alcohol.  
- Children between 6 months and 3 years should not normally be given Clozabam.  
- Amnesia may occur with Benzodiazepines. In case of loss or bereavement, psychological adjustment may be inhibited by Benzodiazepines.  
- In patients with impaired renal or hepatic function, responsiveness to Clozabam and susceptibility to adverse effect are increased and dose reduction may be necessary. In long term treatment, renal and hepatic function must be checked regularly.

**DRUG INTERACTIONS**  
- With the CNS depressant drugs (eg. Analgesics, sedatives and hypnotics).  
- Alcohol are consumed at the same time.  
- If Clozabam is administered simultaneously with anticonvulsants in the treatment of epilepsy, the dosage must be adjusted under regular medical supervision (EEG monitoring).  
- In patients receiving anticonvulsants of Valproic acid and Clozabam, there may be a slight to moderate rise of Valproic acid concentration in plasma.  
- Carbamazepine and phenytoin may cause an increase in the metabolic conversion of Clozabam to N-des-methyl Clozabam.  
- Effect of muscle relaxants, analgesics, and Nitrous oxide may be enhanced.  
- Concurrent treatment with drugs that inhibit the mono-oxygenase system, i.e. Cimetidine, may enhance and prolong the action of Clozabam.

**STORAGE**  
Store at temperature below 30°C, protect from light.  
Keep out of the reach of children.

**PRESENTATION AND REGISTRATION NUMBER**  
Box, 10 Strips @ 10 tablets of Clofritis 10, Reg. No. DP.0433307710A

**For reporting Side Effects and Product Complaints, please contact:**  
**PT. Mersifarma Pharmacovigilance Team**  
Email : .....  
Telephone : 0819-8267-0825

**ON MEDICAL PRESCRIPTION ONLY**

Manufactured by:

**PT. Mersifarma**  
PT. Mersifarma TM  
Sukabumi - Indonesia  
0000-000000-00

Not at scale - Size in mm

**Tablet 10 mg**

Concave tablet with white color tablet, diameter 7 mm, upper initial mf, lower initial blank.

Each Clofritis 10 tablets contains Clobazam .....10 mg

Microcrystalline cellulose pH-102, Lactose monohydrate, Magnesium stearate, Talc, Sodium lauryl sulfate.

Anxiolytic and psychosomatic agent.

Anxiety and psychoneurotic states which may produce symptoms of anxiety.

## Posology

- Adults: 20 mg daily in divided doses, the doses of up to 30 mg daily if needed. In the severe cases the dose should be increased to 60 mg daily.
- Children > 3 years: 5-10 mg daily in divided doses.
- Elderly: 10 - 15 mg daily in divided doses.

The drug is given orally.

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Use in pregnancy and lactation: Clobazam should not be used in the 1<sup>st</sup> trimester of pregnancy and in the later stages, only if there are compelling indication for its use.

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- In patients with sleep apnoea syndrome (risk of deterioration).
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- Dryness of the mouth, constipation, loss of appetite, nausea, dizziness, or a fine tremor of the fingers.
- Treatment with Clobazam should be discontinued if the paradoxical reactions occur eg. restlessness, irritability, acute agitation states, anxiety, suicidal tendencies, frequent muscle spasms.
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- After prolonged use of Benzodiazepines, impairment of consciousness, sometimes combined with respiratory disorders, has been reported in very rare cases.
- Especially in patients receiving high doses or long-term treatment, there may be reversible abnormalities, eg slowing or indistinctness of speech (disorders of articulation), lack of confidence in walking and other motor functions, visual disorders (double vision, nystagmus), weight gain or loss of libido.
- Tolerance physical and/or psychic may develop especially during prolonged use. Discontinuation of the therapy may result in withdrawal or rebound phenomenon. Abuse of Benzodiazepines has been reported.
- When used as an adjunct in the treatment of epilepsy, this preparation may in rare cases cause restlessness and muscle weakness.
- As with other Benzodiazepines, the therapeutic benefit must be balance against the risk of habituation and dependence during prolonged use.

- Special caution is necessary if Clonazepam is to be administered to patients with serious pathological muscle weakness (myasthenia gravis), unsteadiness of movement and gait due to disease of the spinal cord and cerebellum (spinal or cerebellar ataxia), and in case of acute poisoning with alcohol, hypnotics, analgesics, neuroleptic agents, antidepressants or Lithium, in patients with serious liver damage (eg, cholestatic jaundice) and in patients with transient cessation of respiration in sleep (sleep apnoea syndrome). Monitoring of respiratory functions is necessary in patients with severe acute respiratory impairment (respiratory failure).
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- When Benzodiazepines have been taken for a maximum of 4 weeks, the doctor should decide whether the treatment is to be continued. An uninterrupted, prolonged period of administration should be avoided, as it may lead to dependence.
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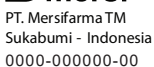
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- Alcohol are consumed at the same time.
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- In patients receiving concurrent treatment of Valproic acid and Clobazam, there may be a slight to moderate rise of Valproic acid concentration in plasma.
- Carbamazepine and phenytoin may cause an increase in the metabolic conversion of Clobazam to N-desmethyl Clobazam.
- Effect of muscle relaxants, analgesics, and Nitrous oxide may be enhanced.
- Concurrent treatment with drugs that inhibit the mono-oxygenase system, i.e. Cimetidine, may enhance and prolong the action of Clobazam.

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Keep out of the reach of children.

Box, 10 Strips @ 10 tablets of Clofritis 10, Reg. No. DPL0433307710A1

**For reporting Side Effects and Product Complaints**  
**PT. Mersifarma Pharmacovigilance Team**  
 Email : farmakovigilans@mersifarma.com  
 Telephone : 0818-8287-0825

Manufactured by:



11N00027

**Tablet 10 mg**

Tablet cembung warna putih diameter 7 mm, muka atas mf, muka bawah polos.

Tiap tablet Clofritis 10 mengandung Clobazam ..... 10 mg

Microcrystalline cellulose pH-102, Lactose monohydrate, Magnesium stearate, Talc, Sodium lauryl sulfate.

Sebagai ansiolitik dan psikosomatik.

Mengatasi keadaan ansietas dan psikoneuritik yang disertai ansietas.

## Posologia

- Dewasa: 20 mg/hari dalam dosis terbagi, jika diperlukan dosis dapat ditingkatkan sampai 30 mg/hari. Untuk kasus berat dapat diberikan sampai 60 mg/hari.
- Anak usia lebih dari 3 tahun: 5 - 10 mg/hari dalam dosis terbagi.
- Penderita usia lanjut: 10 - 15 mg/hari dalam dosis terbagi.

Obat diberikan secara oral.

- Pada pasien yang hipersensitif terhadap Clobazam atau zat-zat lain didalamnya.
- Pasien dengan riwayat ketergantungan obat.
- Penggunaan pada wanita hamil dan menyusui: Jangan digunakan pada kehamilan trimester pertama dan pada bulan bulan selanjutnya, kecuali jika keadaan terpaksa.
- Jangan digunakan pada ibu yang menyusui, karena diekresikan melalui air susu. Jika terpaksa harus diberikan, pemberian air susu ibu harus dihentikan.
- Pada pasien dengan miastenia gravis (risiko kelemahan otot yang semakin parah).
- Pada pasien dengan hambatan penapasan hebat (risiko terjadi deteriorasi).
- Pada pasien dengan sindrom penapasan terhenti sementara pada saat tidur (risiko terjadi deteriorasi).
- Pada pasien dengan kerusakan hati yang parah (risiko ensefalopati).

- Kekeringan pada mulut, konstipasi, hilang nafsu makan, mual, pusing, dan tremor pada jari-jari.
- Pemberian Clonazepam harus dihentikan jika timbul reaksi paradosis seperti gelisah, iritabilitas, agitasi akut, ansietas, kecenderungan melakukan bunuh diri, kejang otot.
- Ataksia, mengantuk, kebingungan, dan sakit kepala.
- Reaksi pada kulit: erupsi atau urtikaria.
- Gangguan fungsi pernapasan ditandai dengan adanya gangguan saluran napas (seperti asma bronkial) dan pada pasien dengan kerusakan otak.
- Setelah penggunaan Benzodiazepine jangka panjang: gangguan kesadaran, kadang timbul juga gangguan pada fungsi pernapasan (jarang sekali terjadi).
- Pada pasien yang menerima dosis tinggi atau penggunaan jangka panjang, akan timbul reaksi abnormal yang *reversible* seperti menjadi lambat atau bicara tidak jelas (gangguan artikulasi bicara), kelemahan kemampuan berjalan dan fungsi motorik yang lain, kerusakan penglihatan (penglihatan ganda, nystagmus), peningkatan berat badan, atau hilang libido.
- Toleransi secara fisik dan/atau psikis dapat terjadi terutama selama penggunaan jangka panjang.
- Penghentian terapi akan menyebabkan *withdrawal* atau *rebound phenomenon*. Ketergantungan terhadap Benzodiazepine telah dilaporkan.
- Pada pengobatan epilepsi, jarang sekali timbul kasus yang menyebabkan kegelisahan dan kelemahan otot.
- Dengan Benzodiazepine lainnya, efek terapi yang diberikan harus seimbang untuk menghindari risiko terjadinya habituasi dan ketergantungan selama penggunaan jangka panjang.

- Perlu diingat peringatan khusus jika Clonazepam diberikan pada pasien yang mengalami kelemahan otot (*Myasthenia gravis*, gerakan yang tidak stabil dan cepat menjadi penyebab kerusakan pada urat saraf tulang belakang dan cerebellum (spinal atau cerebellar ataxia), juga pada kasus keracunan akut karena alkohol, zat hipnotik, analgesik, agen neuroleptik, antidepresan atau Lithium, pada pasien dengan kerusakan hati yang parah (misal, *cholestatic jaundice*) dan pada pasien dengan napas yang terhenti sementara disaat tidur (*sleep apnoea syndrome*). Pemeriksaan fungsi pemapasan pada pasien dengan kerusakan pemapasan akut (kegagalan pemapasan) sangat perlu dilakukan.
- Clonazepam mengandung gugus Benzodiazepine. Benzodiazepine merupakan obat untuk mengatasi gejala seperti gelisah dan ansietas, *inner tension*, dan insomnia. Ada risiko ketergantungan yang dapat timbul saat penggunaan Benzodiazepine, untuk mengurangi risiko yang terjadi, pasien dianjurkan untuk menggunakan obat ini sesuai dengan petunjuk dokter.
- Bila Benzodiazepine digunakan selama maksimum 4 minggu, dokter harus memutuskan apakah pengobatan perlu dilanjutkan. Hindari penggunaan obat yang terlalu lama karena dapat menyebabkan ketergantungan.

Saat penggunaan Benzodiazepine dihentikan setelah penggunaan jangka panjang, maka kegelisahan, ansietas, dan insomnia dapat timbul kembali setelah beberapa hari. Gejala ini biasanya akan hilang setelah 2-3 minggu.

- Konsultasi dengan dokter harus dilakukan jika pasien masih terganggu pada alkohol dan obat. Pada kasus ini, pemakaian Benzodiazepine harus dihentikan kecuali atas petunjuk dokter.
- Pada kondisi percobaan, penurunan kewaspadaan setelah dosis terapi Clonazepam diamati kurang jelas dibandingkan setelah pemberian Benzodiazepine lainnya. Namun, jika Clonazepam digunakan sesuai petunjuk dapat sedemikian rupa mengubah reaktivitas untuk mengurangi kemampuan mengemudi atau kemampuan mengoperasikan mesin, terutama jika digunakan bersama dengan alkohol.
- Penggunaan Clonazepam pada anak-anak umur antara 6 bulan sampai 3 tahun harus dihindari.
- Pemberian Benzodiazepine dapat menyebabkan amnesia. Kondisi berkurangnya kemampuan penyesuaian secara psikologi dapat dihindari dengan Benzodiazepine.
- Pada pasien dengan kerusakan ginjal dan fungsi hati, pengawasan terhadap efek samping Clonazepam harus ditingkatkan, bila perlu dilakukan pengurangan dosis. Pada pengobatan jangka panjang, fungsi ginjal dan hati harus dikontrol secara rutin.

- Dengan obat depresan pada SSP (seperti analgesik, sedatif, dan hipnotik).
- Konsumsi alkohol dalam waktu bersamaan.
- Jika Clobazam diberikan secara simultan dengan antikonvulsan pada pengobatan epilepsi, dosis harus disesuaikan dengan pengawasan kesehatan secara berkala (EEG monitoring).
- Pengobatan bersamaan dengan Valproic acid dan Clobazam: Konersiasi Valproic acid dalam plasma meningkat.
- Carbamazepine dan phenytoin dapat meningkatkan konversi metabolik Clobazam menjadi N-des-methyl Clobazam.
- Efek obat-obat relaksan otot, analgesik, dan Nitrat oksida akan meningkat.
- Pemakaian bersama dengan obat-obat penghambat system mono-oksigenase seperti Cimetidine, dapat meningkatkan dan memperpanjang kerja Clobazam.

**CARA PENYIMPANAN**  
Simpan di bawah suhu 30°C, terlindung dari cahaya.  
Jauhkan obat dari jangkauan anak-anak

Dus, 10 strip @ 10 tablet Clofritis 10, No. Reg. DPL0433307710A1

**Untuk pelaporan Efek Samping dan Keluhan Produk, dapat menghubungi:**  
**Tim Farmakovigilans PT. Mersifarma**  
 Email : farmakovigilans@mersifarma.com  
 Telepon : 0818-8287-0825

**HARUS DENGAN RESEP DOKTER**

Diproduksi oleh:

