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Nergil P1541284

Nergil P1541284

Professional Information for Medicines for Human Use
SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE

NERGIL 25 mg

NERGIL 75 mg

NERGIL 150 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NERGIL 25 mg:
Each capsule contains 25 mg of pregabalin. Sugar free.

NERGIL 75 mg:
Each capsule contains 75 mg of pregabalin. Sugar free.

NERGIL 150 mg:
Each capsule contains 150 mg of pregabalin. Sugar free.
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

NERGIL 25 mg:
Capsules, hard. White cap / White body, size '5' hard gelatine capsule shells, imprinted with "Z" on cap and "10" on body with black ink contains white to off-white granular powder.
The dimensions of the size '5' capsules are as follows:

Length:
6,2 ± 0,4 mm for the cap,
9,3 ± 0,4 mm length for the body

Width:
4,91 ± 0,03 mm for the cap
4,65 ± 0,03 mm for the body

NERGIL 75 mg:
Capsules, hard. Orange cap / White body, size '4' hard gelatine capsule shells, imprinted with "Z" on cap and "12" on body with black ink contains white to off-white granular powder.
The dimensions of the size '4' capsules are as follows:

Length:
7,2 ± 0,4 mm for the cap,
12,2 ± 0,4 mm length for the body

Width:
5,33 ± 0,03 mm for the cap
5,06 ± 0,03 mm for the body

NERGIL 150 mg:
Capsules, hard. White cap / white body, size '2' hard gelatine capsule shells, imprinted with "Z" on cap and "14" on body with black ink contains white to off-white granular powder.
The dimensions of the size '2' capsules are as follows:

Length:
9 ± 0,4 mm for the cap,
15,2 ± 0,4 mm length for the body

Width:
6,37 ± 0,03 mm for the cap
6,08 ± 0,03 mm for the body

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Neuropathic Pain:
NERGIL is indicated for the treatment of neuropathic pain due to Herpes zoster infections and diabetes in adult patients.

4.2. Posology and method of administration

Posology
The recommended starting dose for **NERGIL** is 75 mg twice daily (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.
In accordance with current clinical practice, if **NERGIL** has to be discontinued, it is recommended this should be done gradually over a minimum of 1 week.

Patients with renal impairment:
NERGIL is eliminated from the systemic circulation primarily by renal excretion as unchanged pregabalin. As **NERGIL** clearance is directly proportional to creatinine clearance (see section 5.2– Renal impairment), dosage reduction in patients with compromised renal function must be individualised according to creatinine clearance (CLcr), as indicated in Table 1 determined using the following formula:

$$\text{CLcr (mL/min)} = \frac{(140 - \text{age}) \times \text{Weight (kg)}}{0{,}82 \times \text{serum creatinine (µmol/L)}}$$

* For females multiply the CLcr by 0,85

NERGIL is removed effectively from plasma by haemodialysis (50 % of drug in 4 hours). For patients receiving haemodialysis, the **NERGIL** daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4 - hour haemodialysis treatment (see Table 1)

Table 1: Pregabalin Dose Adjustment Based on Renal Function

Creatinine Clearance (CLcr) (mL/min)	**Total NERGIL Daily Dose***		**Dose Regimen**
	Starting dose (mg/day)	**Maximum dose (mg/day)**	
≥ 60	150	300	BD
30 – 60	75	150	OD or BD
15 – 30	25 – 50	75	OD or BD
< 15	25	25 – 50	OD
Supplementary dosage following haemodialysis (mg)			
	25	50	Single dose+

BD = Two divided doses
OD = Once daily
* Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.
+ Supplementary dose is a single additional dose.
Use in patients with hepatic impairment:
No dosage adjustment is required for patients with hepatic impairment (see section 5.2– Hepatic impairment).

The safety and effectiveness of **NERGIL** in patients below the age of 18 years with neuropathic pain has not been established.

Use in the elderly (over 65 years of age):
No dosage adjustment is necessary for elderly patients unless their renal function is compromised, see Table 1.

Method of administration
NERGIL is given orally with or without food

4.3. Contraindications
NERGIL is contraindicated in patients who are hypersensitive to the active ingredient pregabalin or to any of excipients listed in 6.1.

4.4. Special warnings and precautions for use
Diabetic patients

Diabetic patients who gain weight on **NERGIL** treatment may need to adjust hypoglycaemic medicinal products.
Hypersensitivity reactions
There have been reports of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur.

Dizziness, somnolence, loss of consciousness, confusion and mental impairment
Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. There have also been post marketing reports of loss of consciousness, confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product.

Vision-related effects
Visual adverse reactions have been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient. Discontinuation of **NERGIL** may result in resolution or improvement of these visual symptoms.

Renal failure
Cases of renal failure have been reported and in some cases discontinuation of pregabalin did show reversibility of this adverse reaction.

Withdrawal symptoms
After discontinuation of short-term and long-term treatment with pregabalin, as contained in **NERGIL**, withdrawal symptoms have been observed in some patients. The following events have been mentioned: insomnia, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, hyperhidrosis and dizziness, suggestive of physical dependence. The patient should be informed about this at the start of the treatment.
Convulsions, including status epilepticus and grand mal convulsions, may occur during pregabalin use or shortly after discontinuing pregabalin.
Concerning discontinuation of long-term treatment of **NERGIL**, data suggest that the incidence and severity of withdrawal symptoms may be dose-related.

Congestive heart failure
Congestive heart failure has been reported in some patients receiving pregabalin. These reactions are mostly seen in elderly cardiovascular compromised patients during pregabalin treatment for a neuropathic indication. **NERGIL** should be used with caution in these patients. Discontinuation of **NERGIL** may resolve the reaction.

Suicidal ideation and behaviour
Suicidal ideation and behaviour have been reported in patients treated with gabapentinoids, such as pregabalin in NERGIL, in several indications. Therefore, patients should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered. Patients and caregivers should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

Reduced lower gastrointestinal tract function
Events related to reduced lower gastrointestinal tract function (e.g. intestinal obstruction, paralytic ileus, constipation) have been reported when pregabalin as contained in **NERGIL**, was co-administered with medicines that have the potential to produce constipation, such as opioid analgesics. When **NERGIL** and opioids will be used in combination, measures to prevent constipation may be considered (especially in female patients and elderly).
Concomitant use with opioids
Caution is advised when prescribing **NERGIL** concomitantly with opioids due to risk of CNS depression (see section 4.5). In a case control study of opioid users, those patients who took pregabalin concomitantly with an opioid had an increased risk for opioid-related death compared to opioid use alone (adjusted odds ratio [aOR], 1,68 [95 % CI, 1,19 - 2,36]). This increased risk was observed at low doses of pregabalin (≤ 300 mg, aOR 1,52 [95 % CI, 1,04 - 2,22]) and there was a trend for a greater risk at high doses of pregabalin (> 300 mg, aOR 2,51 [95 % CI 1,24 - 5,06]).

Misuse, abuse potential or dependence
Cases of misuse, abuse and dependence have been reported. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of **NERGIL** misuse, abuse or dependence (development of tolerance, dose escalation, drug- seeking behaviour have been reported).

Encephalopathy
Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate encephalopathy.

4.5. Interaction with other medicines and other forms of interaction
Since pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (< 2 % of a dose recovered in urine as metabolites), does not inhibit drug metabolism *in vitro*, and is not bound to plasma proteins, it is unlikely to produce, or be subject to, pharmacokinetic interactions.

Accordingly, in *in vivo* studies no clinically relevant pharmacokinetic interactions were observed between **NERGIL** and phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. In addition, population pharmacokinetic analysis indicated that the 3 commonly used medicine classes, oral antidiabetics, diuretics and insulin, and the commonly used anti-epileptic medicines, phenytoin, carbamazepine, valproic acid, lamotrigine, phenobarbitone, tiagabine, and topiramate, had no clinically significant effect on pregabalin clearance. Similarly, these analyses indicated that **NERGIL** had no clinically significant effect on the clearance of phenytoin, carbamazepine, valproic acid, lamotrigine, topiramate and phenobarbitone.
Co-administration of **NERGIL** with the oral contraceptives norethisterone and/or ethinyl oestradiol does not influence the steady-state pharmacokinetics of either medicine.
Multiple oral doses of **NERGIL** co-administered with oxycodone, lorazepam, or ethanol did not result in clinically important effects on respiration. **NERGIL** appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone. **NERGIL** may potentiate the effects of ethanol and lorazepam.
There are reports of respiratory failure and coma in patients taking **NERGIL** and other central nervous system depressant medicines.
Interactions and the elderly
No specific pharmacodynamic interaction studies were conducted in elderly volunteers. Interaction studies have only been performed in adults.

4.6. Fertility, pregnancy and lactation
Women of childbearing potential/Contraception in males and females
As the potential risk for humans is unknown, effective contraception must be used in women of child bearing potential.

Pregnancy
There are no adequate data from the use of pregabalin in pregnant women.
Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown.
NERGIL should not be used during pregnancy.

Breastfeeding
Pregabalin is excreted into human milk. The effect of pregabalin on newborns/infants is unknown. Therefore, breastfeeding is not recommended during treatment with **NERGIL**.

Fertility
There are no clinical data on the effects of pregabalin on female fertility.

4.7. Effects on ability to drive and use machines
NERGIL frequently causes dizziness and somnolence. Head and body injuries and road traffic incidents have also been reported with pregabalin as contained in **NERGIL.** Therefore, patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicine affects their ability to perform these activities.

4.8. Undesirable effects
Some cases of hypersensitivity reactions (including angioedema) have been reported with **NERGIL**.
The most common adverse effects associated with **NERGIL** are dizziness, somnolence, loss of consciousness, confusion and mental impairment, with the elderly population the most prone to these adverse effects. Visual adverse reactions (loss of vision and visual blurring) have also been reported but these symptoms have been known to resolve or improve upon discontinuing treatment with **NERGIL** (see section 4.4).
The most commonly reported adverse reactions are tabulated below. The frequencies are defined as follows:
Frequent = more frequent',
Less frequent = 'single reports', 'isolated reports', or 'not frequent'
"Frequency not known" or "frequency unknown" When no frequency data are available for a specific ADR, the statement added.

Tabulated list of adverse reactions

System Organ Class	**Adverse drug reactions**
Infections and infestations	
Frequent	Nasopharyngitis
Blood and lymphatic system disorders	
Less frequent	Neutropenia
Immune system disorders	
Less frequent	Hypersensitivity Angioedema, allergic reaction
Metabolism and nutrition disorders	
Frequent	Appetite increased
Less frequent	Anorexia, hypoglycaemia
Psychiatric disorders	
Frequent	Euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased
Less frequent	Hallucination, panic attack, restlessness, agitation, depression, depressed mood, elevated mood, aggression, mood swings, insomnia, depersonalisation, word finding difficulty, abnormal dreams, libido increased, anorgasmia, apathy, disinhibition, elevated mood
Frequency unknown	Suicidal ideation and behaviour
Nervous system disorders	
Frequent	Dizziness, somnolence, headache, ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypaesthesia, sedation, balance disorder, lethargy
Less frequent	Syncope, stupor, myoclonus, loss of consciousness, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, mental impairment, speech disorder, visual field defect, hyporeflexia, hyperaesthesia, burning sensation, ageusia, malaise, convulsions, parosmia, hypokinesia, dysgraphia
Eye disorders	
Frequent	Vision blurred, diplopia
Less frequent	Visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, dry eye, lacrimation increased, eye irritation, photopsia, vision loss, keratitis, oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness, peripheral vision loss
Ear and labyrinth disorders	
Frequent	Vertigo
Less frequent	Hyperacusis
Cardiac disorders	
Less frequent	Tachycardia, congestive heart failure, atrioventricular block first degree, sinus bradycardia, QT prolongation, sinus tachycardia, sinus dysrhythmia
Vascular disorders	
Less frequent	Hot flushes, flushing, hypotension, hypertension, peripheral coldness
Respiratory, thoracic and mediastinal disorders	
Less frequent	Respiratory depression /dyspnoea, nasal dryness, epistaxis, nasopharyngitis cough, nasal congestion, rhinitis, snoring, pulmonary oedema, throat tightness
Gastrointestinal disorders	
Frequent	Vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth
Less frequent	Gastroesophageal reflux disease, salivary hypersecretion, hypaesthesia oral, ascites, pancreatitis, swollen tongue, dysphagia
Hepatobiliary disorders	
Less frequent	Elevated liver enzymes, jaundice, hepatic failure, hepatitis
Skin and subcutaneous tissue disorders	
Less frequent	Rash papular, sweating, urticaria, hyperhidrosis, pruritus, Stevens Johnson syndrome, cold sweat
Musculoskeletal and connective tissue disorders	
Frequent	Muscle cramp, back pain, pain in limb, cervical spasm
Less frequent	Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness, arthralgia, rhabdomyolysis
Renal and urinary disorders	
Less frequent	Urinary incontinence, dysuria, renal failure, oliguria, urinary retention
Reproductive system and breast disorders	
Frequent	Erectile dysfunction
Less frequent	Sexual dysfunction, ejaculation delayed, dysmenorrhoea, amenorrhoea, breast discharge, breast enlargement, breast pain, gynaecomastia

DETACH BEFORE DISPENSING

Patient Information Leaflet

S5
NERGIL 25 mg
NERGIL 75 mg
NERGIL 150 mg
Pregabalin. Sugar free.

Read all of this leaflet carefully before you start taking NERGIL.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **NERGIL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:
1. What **NERGIL** is and what it is used for
2. What you need to know before you use **NERGIL**
3. How to use **NERGIL**
4. Possible side effects
5. How to store **NERGIL**
6. Contents of the pack and other information

1. What NERGIL is and what it is used for
NERGIL belongs to a group of medicines used to treat neuropathic pain due to Herpes zoster infections and diabetes in adults.

2. What you need to know before you take NERGIL
Do not take NERGIL:
If you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with NERGIL:
- If you start taking **NERGIL** and experience swelling of the face, lips, tongue, and throat, as well as skin reaction and you should contact your healthcare practitioner immediately.
- If you are taking diabetes medicine and gain weight whilst taking **NERGIL** talk to your doctor as he/she may need to alter the dose of your diabetes medicine.
- **NERGIL** can cause dizziness and somnolence, which can increase the occurrence of accidental injury (fall). **NERGIL** until you are used to how you react to it.
- **NERGIL** may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience decreased urination whilst taking **NERGIL** you should tell your doctor.
- Stopping treatment with **NERGIL** after short and long term use may cause withdrawal symptoms such as: difficulty sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, excessive sweating and dizziness.
- If you suffer from or have a family history of heart disease, tell your doctor, before commencing treatment with **NERGIL**.
- If you start treatment with **NERGIL** and have thoughts of harming or killing yourself, you should immediately tell your doctor.
- **NERGIL**, when taken with other medicines (certain pain medicines) may cause gastrointestinal problems (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking **NERGIL** you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease because taking **NERGIL** while suffering from such conditions may result in a reduction in brain function (encephalopathy).

Other medicines and NERGIL:
Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

NERGIL interacts with the following medicines:
- Oxycodone – (used as a pain killer)
- Lorazepam – (used for treating anxiety)
- Alcohol

Taking the above with **NERGIL** may lead to excess dizziness, sleepiness and decreased concentration which could lead to respiratory failure, coma and death.

NERGIL with food, drink and alcohol
There are no noted interactions between food and **NERGIL**. **NERGIL** should not be taken with alcohol.

Pregnancy, breastfeeding and fertility
NERGIL should not be taken during pregnancy or when breastfeeding, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing age.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines
NERGIL may cause dizziness, sleepiness and decreased concentration. Head and body injuries and road traffic incidents have been reported with **NERGIL**. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether **NERGIL** affects your ability to perform these activities.

3. How to take NERGIL
Do not share medicines prescribed for you with any other person.
Always take **NERGIL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **NERGIL** will last. If you have the impression that the effect of **NERGIL** is too strong or too weak, talk to your doctor or pharmacist.
The usual recommended starting dose for **NERGIL** is 75 mg twice daily (150 mg/day), with or without food. This dose may be increased to 150 mg twice daily after an interval of 3 to 7 days. **NERGIL** is for oral use only.
If you are an elderly patient (over 65 years of age), you should take **NERGIL** normally except if you have problems with your kidneys. You have to discuss this with your doctor.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.
Swallow the capsule whole with water.

Continue taking **NERGIL** until your doctor tells you to stop.

If you take more NERGIL than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

You may feel sleepy, confused, agitated, or restless as a result of taking more **NERGIL** than you should. Fits have also been reported.

If you forget to take NERGIL
If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
NERGIL can have side effects:
Not all side effects reported for **NERGIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NERGIL**, please consult your healthcare provider for advice.
If any of the following happens, stop taking **NERGIL** and tell your doctor immediately or go to the casualty department at your nearest hospital: if someone experiences symptoms of respiratory problems because these can lite threatening.

Symptoms to watch for include:
- Confusion or disorientation,
- Unusual dizziness or lightheadedness,
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness, which means the person does not answer or react normally or when you wake them up.
- Bluish-coloured or tinted skin, especially on the lips, fingers, and toes'
- inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain

These are all very serious side effects. If you have them, you may have had a serious reaction to **NERGIL**. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
The following side effects occur frequently:
- swelling of your face (around lips and eyes), nausea, abdominal pain, fatigue and fever
- decreased urinary output, swelling of your legs, ankles and feet
- dark, reddish urine, a decreased amount of urine, weakness and muscle aches

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- nausea, vomiting
- diarrhoea, constipation, flatulence
- feeling bloated
- dry mouth
- increased appetite
- mood changes, confusion, irritability, disorientation
- difficulty sleeping
- decreased libido
- dizziness, excessive sleepiness, headache
- symptoms of ataxia which can be impaired balance and coordination, slurring, coordination abnormal, tremor
- dysarthria, amnesia, memory impairment, disturbance in attention
- tingling or prickling sensation (paraesthesia), reduced sense of touch or sensation (hypoesthesia)
- sedation, balance disorder, lethargy
- blurred vision, double vision
- vertigo (spinning sensation)
- muscle cramp, muscle pain, back pain, spasm
- erectile dysfunction
- changes in the way you walk, fall, feeling fatigued
- weight gain

Less frequent side effects:
- low white blood cell count, leaving you prone to infections
- decreased blood sugar levels
- anorexia
- seeing, feeling or hearing things that are not there
- panic attack, restlessness, agitation, depression, depressed mood, elevated mood, aggression, mood swings, insomnia, depersonalisation, word finding difficulty, abnormal dreams
- increase libido, inability to orgasm
- loss of interest, or ability to orgasm
- impulsive behaviour, lack of restraint
- abnormal movement of lips and face, jerky movements of the muscles
- dizziness postural, intention tremor
- uncontrolled movements of the eye
- mental impairment, speech disorder
- absent reflexes
- loss of taste function of the tongue
- feeling unwell
- convulsions
- loss of ability to detect smell
- decreased body movement
- learning disability in the form of poor writing
- peripheral vision loss, visual disturbance, eye swelling, visual field defect, eye pain
- eye strain, experiencing flashes of light in the field of vision
- dry eye
- increase flow of tears, eye irritation
- inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain
- decreased visual depth perception, pupil dilation, visual brightness
- hearing sensitivity
- slow, fast, irregular or abnormal heartbeat, heart problems
- increase or decrease in blood pressure, hot flushes feelingcold
- shortness of breath, cough, nasal congestion and dryness, snoring
- collection of fluid in the lungs
- difficulty swallowing, swelling of the tongue, increased saliva production, heartburn, numb around mouth
- muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- delayed ejaculation

5. How to store NERGIL
Store at or below 25 °C.
Keep the blisters in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What NERGIL contains:
NERGIL contains the active substance pregabalin. The other ingredients of **NERGIL** are:
- Maize starch Ph.Eur
- Talc Ph.Eur
- Empty hard gelatine capsule shell

NERGIL 25 mg
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E171).

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NERGIL 75 mg
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E171)
- Iron oxide red (E No: 172)

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NERGIL 150 mg:
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E171)

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

What NERGIL looks like and contents of the pack
NERGIL 25 mg:
Capsules, hard. White cap / White body, size '5' hard gelatine capsule shells, imprinted with "Z" on cap and "10" on body with black ink contains white to off-white granular powder.
The dimensions of the size '5' capsules are as follows:

Length:
6,2 ± 0,4 mm for the cap, 9,3 ± 0,4 mm length for the body

Width:
4,91 ± 0,03 mm for the cap 4,65 ± 0,03 mm for the body

NERGIL 75 mg:
Capsules, hard. Orange cap / white body, size '4' hard gelatine capsule shells, imprinted with "Z" on cap and "12" on body with black ink contains white to off-white granular powder.
The dimensions of the size '4' capsules are as follows:

Length:
7,2 ± 0,4 mm for the cap, 12,2 ± 0,4 mm length for the body

Width:
5,33 ± 0,03 mm for the cap 5,06 ± 0,03 mm for the body

NERGIL 150 mg:
Capsules, hard. White cap / white body, size '2' hard gelatine capsule shells, imprinted with "Z" on cap and "14" on body with black ink contains white to off-white granular powder.
The dimensions of the size '2' capsules are as follows:

Length:
9 ± 0,4 mm for the cap, 15,2 ± 0,4 mm length for the body

Width:
6,37 ± 0,03 mm for the cap 6,08 ± 0,03 mm for the body

NERGIL 25 mg
Blister Pack:
Capsules are packed in an aluminium foil blister pack.
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

NERGIL 75 mg
Blister Pack:
Capsules are packed in an aluminium foil blister pack.
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

NERGIL 150 mg
Blister Pack:
Capsules are packed in an aluminium foil blister pack
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

HOLDER OF THE CERTIFICATE OF REGISTRATION
Aurogen SA (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Edkins Crescent Avenue
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1448, Johannesburg South Africa

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Registration number
NERGIL 25mg: 48/2.5/1073
NERGIL 75mg: 48/2.5/1074
NERGIL 150mg: 48/2.5/1075

A/s: 420 x 660 mm ■ Black

AUROBINDO Packaging Development	Product Name	Component	Item Code	Date & Time
	Nergi Tablets	Leaflet	P1541284	17.12.2025 & 06.10 pm
	Country	**Version No.**	**Reason Of Issue**	**Reviewed / Approved by**
	Aurogen-South africa-U15	01	Submission	
Team Leader Kiran K	**Dimensions (mm)**	**Colours: 01**		
Initiator Bhogi	A/s: 420 x 660 mm	41284		
Artist MJ Designers Chandrasekhar	Pharma Code: 41284			
Additional Information: **Supersede Code: P1535191**				

General disorders and administration site conditions	
Frequent	Oedema peripheral, oedema, gait abnormal, feeling drunk, feeling abnormal, fatigue
Less frequent	Generalised oedema, face oedema, fall, chest tightness, pain, pyrexia, thirst, chills, asthenia
Investigations	
Frequent	Weight increased
Less frequent	Alanine aminotransferase increased, aspartate aminotransferase increased, blood creatine phosphokinase increased, platelet count decreased, white blood cell count decreased, blood glucose increased, blood creatinine increased, blood potassium decreased, weight decreased

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Medicine Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9. Overdose
In the post marketing experience, the most commonly reported adverse reactions observed when pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness. Seizures were also reported.

In rare occasions, cases of coma have been reported.

Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary (see section 4.2 Table 1).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Category and Class: A 2.5 Central nervous system depressants - Anticonvulsants; including antiepileptics.
Pharmacotherapeutic group: Anti-epileptics, other anti-epileptics ATC code: N03AX16

Mechanism of action
Pregabalin is a gamma-aminobutyric acid (GABA) analogue ((S)-3- (aminomethyl)-5- methylhexanoic acid). It binds to an auxiliary subunit (α_2–δ protein) of voltage-gated calcium channels in the central nervous system, potently displacing [3H]-gabapentin. In animal models it was shown that binding of pregabalin to the α_2–δ site is required for analgesic activity.

5.2. Pharmacokinetic properties
Pregabalin steady-state pharmacokinetics are similar in healthy volunteers, and patients with chronic pain.

Absorption
Pregabalin is absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥ 90 % and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in Cmax by approximately 25-30 % and a delay in t_{max} to approximately 2,5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution
In preclinical studies, pregabalin has been shown to cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. In humans, the apparent volume of distribution of pregabalin following oral administration is approximately 0,56 l/kg. Pregabalin is not bound to plasma proteins.

Biotransformation
Pregabalin undergoes negligible metabolism in humans. Following a dose of radiolabelled pregabalin, approximately 98 % of the radioactivity recovered in the urine was unchanged pregabalin. The N-methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0,9 % of the dose. In preclinical studies, there was no indication of racemisation of pregabalin S-enantiomer to the R-enantiomer.

Elimination
Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.

Pregabalin mean elimination half-life is 6,3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance (see section 5.2 Renal impairment).

Dose adjustment in patients with reduced renal function or undergoing haemodialysis is necessary (see section 4.2 Table 1).

Linearity/non-linearity
Pregabalin pharmacokinetics are linear over the recommended daily dose range. Inter-subject pharmacokinetic variability for pregabalin is low (< 20 %). Multiple dose pharmacokinetics are predictable from single-dose data. Therefore, there is no need for routine monitoring of plasma concentrations of pregabalin.

Renal impairment
Pregabalin clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by haemodialysis (following a 4 hour haemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50 %). Because renal elimination is the major elimination pathway, dose reduction in patients with renal impairment and dose supplementation following haemodialysis is necessary (see section 4.2 Table 1).

Hepatic impairment
No specific pharmacokinetic studies were carried out in patients with impaired liver function. Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged drug in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Elderly
Pregabalin clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age related compromised renal function (see section 4.2 Table 1).

5.3 Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
The other ingredients of NERGIL are:
- Maize starch Ph.Eur
- Talc Ph.Eur
- Empty hard gelatine capsule shell

NERGIL 25 mg:
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine,
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171).

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NERGIL 75 mg:
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine,
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171)
- Iron oxide red (E No: 172)

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NERGIL 150 mg:
1. Constituents of the capsule:
The capsule shell contains:
- Gelatine,
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171)

2. Constituents of the printing ink:
The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

6.2. Incompatibilities
Not applicable

6.3. Shelf life
3 years

6.4. Special precautions for storage
Store at or below 25 °C.
Keep the blisters in the carton until required for use.
Keep all medicines out of the reach and sight of children

6.5. Nature and contents of container
NERGIL 25 mg

1) Blister Pack:
Capsules are packed in an aluminium foil blister pack.
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

NERGIL 75 mg

1) Blister Pack:
Capsules are packed in an aluminium foil blister pack.
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

NERGIL 150 mg

1) Blister Pack:
Capsules are packed in an aluminium foil blister pack.
Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
No special requirements for the disposal and handling of **NERGIL.**

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
AUROGEN SA (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448 Johannesburg
South Africa

8. REGISTRATION NUMBER
NERGIL 25mg: 48/2.5/1073
NERGIL 75mg: 48/2.5/1074
NERGIL 150mg: 48/2.5/1075

9. DATE OF FIRST AUTHORISATION
08 DECEMBER 2020

10. DATE OF REVISION OF TEXT
15 December 2025

P1541284

DETACH BEFORE DISPENSING

Pasiëntinligtingsblad

55

NERGIL 25 mg
NERGIL 75 mg
NERGIL 150 mg

Pregabalin
Suikervry

Lees hierdie hele blad noukeurig deur voordat u begin om NERGIL te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- **NERGIL** is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is:
1. Wat **NERGIL** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **NERGIL** gebruik
3. Hoe om **NERGIL** te gebruik
4. Moontlike newe-effekte
5. Hoe om **NERGIL** te bêre
6. Inhoud van die pak en ander inligting

1. Wat NERGIL is en waarvoor dit gebruik word
NERGIL behoort aan 'n groep medisyne wat gebruik word om neuropatiese pyn as gevolg van Herpes zoster-infeksies en diabetes in volwassenes te behandel.

2. Wat u moet weet voordat u NERGIL drink
Moenie NERGIL drink nie:
As u allergies vir pregabalin of vir enige van die ander bestanddele van hierdie medisyne is (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls
Wees veral versiglig met NERGIL:
- As u **NERGIL** begin drink en swelling van die gesig, lippe, tong en keel ervaar, sowel as diffuse veluitslag. Dit is simptome van 'n allergiese reaksie, en u moet u gesondheidspraktisyn dadelik skakel.
- As u medisyne vir diabetes drink en gewig optel terwyl u **NERGIL** drink, moet u moet u dokter diabetesmedisyne verander.
- **NERGIL** kan duiseligheid en slaperigheid veroorsaak, wat die voorkoms van toevallige beserings u **NERGIL** drink totdat u gewoond is aan hoe u daarop reageer.
- **NERGIL** kan dowwe visie of verlies van visie of ander veranderings in sig veroorsaak. As u ondervind minder urinering of dokter se.
- Staking van behandeling met **NERGIL** na kort of langdurige gebruik kan onttrekkingsimptome naarheid, angs, diarree, griepsindroom, senuweeagtigheid, depressie, pyn, stuiptrekkings, oo
- As u aan hartsiektes ly of 'n familiegeskiedenis daarvan het, moet u dit vir u dokter sê voordat
- As u moet **NERGIL** begin en u drink om vaardigheid te bestuur te maak, moet u dit dadelik vr
- **NERGIL** kan duiseligheid, verwardheid en slaperigheid veroorsaak, wat die risiko van ongelukke medisyne vir gevrydheid gedrink word. Sê vir u dokter as u ligaamsbeserings ervaar, veral as u gereeld
- Voordat u **NERGIL** drink, moet u vir u dokter sê as u 'n geskiedenis van alkoholisme of dwelm medisyne drink as wat voorgeskryf is nie.
- Sê vir u dokter as u 'n geskiedenis van ernstige mediese toestande het, waaronder lewer- of n in breinfunksie (ensefalopatie) kan lei as u aan sulke toestande lei.

Ander medisyne en NERGIL:
Sê altyd vir u dokter, apteker of verpleegkundige as u enige ander medisyne gebruik (dit sluit alle aanvullende en tradisionele veroorsaak.

NERGIL interageer moontlik met die volgende medisyne:
- Okskodon (word as pynstiller gebruik)
- Lorazepaam (vir die behandeling van angs gebruik)
- Alkohol

Gebruik van bogenoemde saam met **NERGIL** kan tot oormatige duiseligheid, slaperigheid en swak konsen veroorsaak.

NERGIL saam met kos, drank en alkohol
Daar is geen bekende interaksies tussen voedsel en **NERGIL** nie. **NERGIL** moet nie saam met alkohol geb

Swangerskap, borsvoeding en vrugbaarheid
NERGIL moet nie tydens swangerskap of tydens borsvoeding gedrink word nie, tensy u dokter anders vrugbare ouderdom gebruik word.

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u dokter advies raadpleeg voordat u hierdie medisyne drink.

Motorhestuur en gebruik van masjinerie
NERGIL kan duiseligheid, slaperigheid en swak konsentrasie veroorsaak. Kop- en ligaamsbeserings en **NERGIL** aangemeld. U mag nie bestuur, ingewikkelde masjinerie gebruik of aan ander potensieel gevaarlik vermoë om hierdie aktiwiteite uit te voer, beïnvloed.

3. Hoe om NERGIL te drink
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Gebruik **NERGIL** altyd presies soos vat u dokter vir u gesê het. Raadpleeg u dokter of apteker as u nie sek
NERGIL sal duur. Praat met jou dokter of apteker as jy die indruk het dat die effek van **NERGIL** te sterk of
Die gewone aanbevolle aanvangsdosis van **NERGIL** is 75 mg twee keer per dag (150 mg/dag), met of sonc
dae tot 150 mg twee keer per dag verhoog word. **NERGIL** is slegs vir mondelinge gebruik.

As u 'n bejaarde pasiënt is (ouer as 65 jaar), moet u **NERGIL** normaal gebruik, behalwe as u probleme me
U dokter kan 'n ander dosisskedule enkel dosis voorskryf as u probleme met u niere het.
Sluk die kapsule heel met water af.

Hou aan om **NERGIL** te drink totdat u dokter vir u sê om op te hou.

As u meer NERGIL gedrink het as wat u moes
Raadpleeg jou dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste
U voel dalk slaperig, verward, prikkelbaar of onrusig as u meer **NERGIL** drink as wat u moes. Toevalle is

As u vergeet om NERGIL te drink
As u vergeet om 'n dosis te drink, drink dit sodra as wat u dit onthou, behalwe as dit bykans tyd vir u volg
vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte
NERGIL kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir **NERGIL** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesk
ervaar terwyl u **NERGIL** drink, moet u u gesondheidsorgverskaffer asseblief om advies raadpleeg.

Indien enige van die volgende gebeur of as iemand simptome van asemhalingsprobleme ondervind, hou
of gaan na die ongevalle-afdeling toe by jou naaste hospitaal as u enige van die volgende simptome
Simptome om voor uit te kyk sluit in:
- Verwardheid of delirium.
- Verminderde of afgestomde waarnemingsvermoë of hoofdigheid.
- Buitensporige slaperigheid of lusteloosheid.
- Stadige, vlak of moeisame asemhaling.
- Onreadelwheid, wat beteken dat die persoon nie antwoord of normaal reageer wanneer jy hulle wakker maak nie.
- Blouerige of verkleurde vel, veral die lippe, vingers en tone.

Ontsteking van die oë (keratitis) en ernstige velreaksie wat gekenmerk word deur uitslag, blase, afskilferende vel en pyn.
Dit is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op **NERGIL** het.
Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.
Sê dadelik vir u dokter of gaan na die ongevalle-afdeling toe as u enige van die volgende newe-effekte
Die volgende newe-effekte kom dikwels voor:
- geelsug (geel verkleuring van die vel en oë), naarheid, buikpyn, moegheid en koors
- minder urienuitset, swelling van u bene, enkels en voete
- donker, rooierige urien, 'n kleiner hoeveelheid urien, swakheid en spierpyn

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:
- naarheid, braking
- diarree, hardlywigheid, winderigheid
- voel opgeblase
- droë mond
- toename in eetlus
- buierigheid, verwardheid, geïrriteerdheid, disoriëntasie
- probleme om te slaap
- laer libido
- duiseligheid, oormatige slaperigheid, hoofpyn
- simptome van ataksie wat balans en koördinasie kan benadeel, sleepspraak, abnormale koördi
- disartrie, geheueverlies, geheueverswakking, aandagversteuring
- tintelende of prikkelende sensasie (parestesie), swakker tassin of tassensasie (hipoëstesie)
- sedasie, batainsversteuring, lusteloosheid
- dowwe visie, dubbelvisie
- vertige (gevoel van in die rondte draai)
- spierkramps, spierpyn, rugpyn, spasma
- gewrigsteurnis, swelling
- verskeidenheid seksuele manier waarop mens loop, struikeling, voel moeg
- toename in gewig

Newe-effekte wat minder dikwels voorkom:
- lae aantal witbloedselle, wat u geneig maak tot infeksies
- lae bloedsuikervlakke
- anoreksie
- sien, voel en hoor goed wat nie daar is nie
- abnormale droom
- hoër libido, onvermoë tot orgasme
- gebrek aan belangstelling of entnesiasme
- impulsiewe gedrag, gebrek aan selfbeheersing
- tydelike verlies van bewussyn
- abnormale beweging van die lippe en gesig, rukkerige bewegings van die spiere
- posturale duiseligheid intensietremor
- onbeheerde bewegings van die oë
- geestesgestremdheid spraakversteuring
- geen refleksie nie
- verlies van smaakfunksie van die tong
- voel siek
- konvulsies
- minder ligpaamsbeweging
- leergestremdheid in die vorm van swak skryfwerk
- verlies van perifere visie, gesigversteuring, swelling in die oë, dietek in die gesigsveld, oogpyn
- oogspanning, ervaar iniese van ligin die gesigsveld
- droë oë
- meer vloei van trane, oogirritasie
- visieverlies, ontsteking van die kornea
- veranderde visuele diepteperseopsie, verwyding van die pupille, helder visie
- gehoorgevoeligheid
- stadige, vinnige, onreëlmatige of abnormale hartklop, hartprobleme
- styging of daling in bloeddruk, warm gloede, voel koud
- kortasemheid, hoes, toe en droë neus, snork
- longedeem of vloeistof in die longe
- slukprobleme, swelling van die tong, meer speekselproduksie, sooibrand, gevoelloosheid om die
- spiertrekkings, gewrigsswelling, spierstyfheid, pyn waaronder spierpyn, rekpyn
- vertraagde ejakulasie
- menstruele krampe, onreëlmatige menstruasie, pyn in die borste, afskeiding uit borste en vergrot
- ontwikkeling van borste in mans
- benoudheid, pyn, koors, doors, kouekoors, abnormale liggaamlike swakheid of gebrek aan energie
- veranderinge in bloed- en lewertoetsresultate (hoër vlakke kreatinientfosfokinase in bloed, hoër vla aspartaataminotransferase, minder bloedplaatjies, neutropenie, toename in kreatinien in bloed, af
- hoër geneigdheid tot bloeding
- lae bloedplaatjietelling, wat tot ergse bloeding lei
- neusbloeding
- droë mond
- inflammasie van die lewer
- gewrigspyn, seer spiere waaronder spierkramps
- abnormale lisiese swakheid of gebrek aan energie

Newe-effekte met onbekende frekwensie, selftoodgedates en -gedrag
As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblie

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. Dit sluit alle moontlike newe-effekte in effekte ook via https://www.sahpra.org.za/Publications/Index/8 aanmeld. Deur newe-effekte aan te meld, kan hierdie medisyne te gee.

5. Hoe om NERGIL te bêre
Bêre by of onder 25 °C.
Hou die stulpstroke in die karton totdat dit benodig word.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Gee alle ongebruikte medisyne terug aan u apteker.
Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting
Wat NERGIL bevat
NERGIL bevat die aktiewe stof pregabalin. Die ander bestanddele van **NERGIL** is:
- mieliestysel Eur. Ph.
- talk Eur. Ph.
- leë hardegelatienkapsuledop

NERGIL 25 mg:
1. Bestanddele van die kapsule:
Die kapsuledop bevat:
- gelatien
- natriumlourietsulfaat
- water
- titaandioksied (CI No: 77891 en E No: E 171).

2. Bestanddele van die drukink:
Die drukink bevat:
- Skellak
- gedehidreerde alkohol
- isopropielalkohol
- butielalkohol
- propileenglikol
- sterk ammoniakoplossing
- swart ysteroksied (CI No: 77499)
- kaliumhidroksied
- gesuiwerde water

NERGIL 75 mg:
1. Bestanddele van die kapsule:
Die kapsuledop bevat:
- gelatien
- natriumlourietsulfaat
- water
- titaandioksied (CI No: 77891 en E No: E 171).
- rooi ysteroksied (E No: 172)

2. Bestanddele van die drukink:
Die drukink bevat:
- Skellak
- gedehidreerde alkohol
- isopropielalkohol
- butielalkohol
- propileenglikol
- sterk ammoniakoplossing
- swart ysteroksied (CI No: 77499)
- kaliumhidroksied
- gesuiwerde water

NERGIL 150 mg
1. Bestanddele van die kapsule:
Die kapsuledop bevat:
- gelatien
- natriumlourietsulfaat
- water
- titaandioksied (CI No: 77891 en E No: E 171).

2. Bestanddele van die drukink:
Die drukink bevat:
- Skellak
- gedehidreerde alkohol
- isopropielalkohol
- butielalkohol
- propileenglikol
- sterk ammoniakoplossing
- swart ysteroksied (CI No: 77499)
- kaliumhidroksied
- gesuiwerde water

Hoe NERGIL lyk en die inhoud van die pakkie
NERGIL 25 mg:
Kapsules, hard: Wit doppie/wit romp, grootte 5 hardegelatienkapsuledoppies, met "2" in swart ink op die doppie en "10" op die romp gedruk en bevat wit tot afwit korrelagtige poeier.

Die afmetings van die grootte 5 kapsules is as volg:

Lengte:
6,2 ± 0,4 mm vir die doppie, 9,3 ± 0,4 mm vir die romp

Breedte:
4,91 ± 0,03 mm vir die doppie, 4,65 ± 0,03 mm vir die romp

NERGIL 75 mg:
Kapsules, hard: Oranje doppie/wit romp, grootte 4 hardegelatienkapsuledoppies, met "7" in swart ink op die doppie en "12" op die romp gedruk en bevat wit tot afwit korrelagtige poeier.

Die afmetings van die grootte 4 kapsules is as volg:

Lengte:
7,2 ± 0,4 mm vir die doppie, 12,2 ± 0,4 mm vir die romp

Breedte:
5,33 ± 0,03 mm vir die doppie, 5,06 ± 0,03 mm vir die romp

NERGIL 150 mg:
Kapsules, hard: Wit doppie/wit romp, grootte 2 hardegelatienkapsuledoppies, met "2" in swart ink op die doppie en "14" op die romp gedruk en bevat wit tot afwit korrelagtige poeier.

Die afmetings van die grootte 2 kapsules is as volg:

Lengte:
9 ± 0,4 mm vir die doppie, 15,2 ± 0,4 mm vir die romp

Breedte:
6,37 ± 0,03 mm vir die doppie, 6,08 ± 0,03 mm vir die romp

NERGIL 25 mg
Stulppak:
Kapsules in 'n stulppak van aluminiumfoelie verpak.
Pakgrootte: 60 kapsules - elke karton bevat 6 stulpstroke met 10 kapsules elk.

NERGIL 75 mg
Stulppak:
Kapsules in 'n stulppak van aluminiumfoelie verpak.
Pakgrootte: 60 kapsules - elke karton bevat 6 stulpstroke met 10 kapsules elk.

NERGIL 150 mg
Stulppak:
Kapsules in 'n stulppak van aluminiumfoelie verpak.
Pakgrootte: 60 kapsules - elke karton bevat 6 stulpstroke met 10 kapsules elk.

HOUER VAN DIE REGISTRASIESERTIFIKAAT
Aurogen SA (Edms) Bpk
Woodhillkantoorpark, Gebou 1, Eerste vloer
53 Phillip Engelbrechtlaan 53
Meyersdal Uitbr. 12,
1448, Johannesburg
Suid-Afrika

Hierdie blad is laas hersien op:
15 Desember 2025

Registrasienommers
NERGIL 25mg: 48/2.5/1073
NERGIL 75 mg: 48/2.5/1074
NERGIL 150mg: 48/2.5/1075