

Brigalin Capsule

Pregabalin (75mg & 150mg)

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What Brigalin is used for

It is used to treat:

- Neuropathic pain
Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.
- Epilepsy
Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.
- Generalised anxiety disorder
Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
- Fibromyalgia
Pregabalin is indicated for the management of fibromyalgia.

How Brigalin works

Brigalin helps to decrease the number of nerve signals thus calm down overly sensitive nerve cells.

Before you use Brigalin

When you must not take it

Do not take Brigalin if you:

- Are allergic (hypersensitive) to Pregabalin or any ingredients in this medicine. See the end of this leaflet for a complete list of ingredients in Brigalin.
- Symptoms of an allergic reaction to Brigalin may include:
 - Serious, even life-threatening allergic reactions
 - Suicidal thoughts or actions

- Swelling of your hands, legs and feet
- Dizziness and sleepiness

Pregnancy and lactation

Animal studies have shown that pregabalin, the active ingredient in Brigalin, causes reproductive toxicity. Hence it should not be taken during pregnancy. Effective contraception must be used in women of child bearing potential.

Brigalin is excreted in the milk of lactating women. As the safety of Brigalin in infants is not known, breast-feeding is not recommended during treatment with Brigalin.

You and your healthcare provider should discuss whether you should take Brigalin or breast-feed, but you should not do both.

Before you start to take it

Tell your doctor or pharmacist about all your medical conditions including if you:

- have or had depression, mood problems or suicidal thoughts or behaviour.
- have kidney problems or get kidney dialysis
- have heart problems including heart failure
- have a bleeding problem or a low blood platelet count
- have abuse prescription medicines, or street drugs in the past
- have ever had swelling in your face, mouth (tongue, lips, gums) and neck (throat and larynx; angioderma)
- are in first trimester of pregnancy as Brigalin may cause major birth defects in the unborn child.
- have or had indigestion to milk or milk products (lactose intolerance)
- have brain malfunction (encephalopathy)
- have had cases of misuse, abuse and dependence (drug-seeking behavior) in the past
- are undergoing treatment of central neuropathic pain due to spinal cord injury
- have existing slow and ineffective breathing, or if you are taking a

group of medicines called CNS depressants, including opioids.

Taking other medicines

Tell your doctor or pharmacist about all the medicines you take, including prescription and nonprescription medicines, vitamins or herbal supplements. Brigalin and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Angiotensin converting enzyme (ACE) inhibitors, which are used to treat many conditions, including high blood pressure. You may have a higher chance for swelling and hives if these medicines are taken with Brigalin. See Section 5 “While you are using Brigalin”.
- Avandia (rosiglitazone), Avandamet (contains rosiglitazone and metformin), or Actos (pioglitazone) for diabetes.
You may have a higher chance of weight gain or swelling of your hands or feet if these medicines are taken with Brigalin. See Section 6. “Side Effects”.
- Any medicines that make you sleepy.
- Brigalin may increase the effects of ethanol and lorazepam.
- Brigalin appears to increase certain effects (impairment of thought process and gross bodily movements) caused by oxycodone.
- There are reports of lung failure, coma and deaths in patients taking Brigalin and other central nervous system depressant medications, including in patients who are drug abusers.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking to your healthcare provider.

How to use Brigalin

How much to take

- Take Brigalin exactly as prescribed. Your healthcare provider will tell you how much Brigalin to take.

- Brigalin may be taken with or without food.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- The dose range is 150 to 600 mg per day given in either two or three divided doses.

When to take Brigalin

Take Brigalin exactly as prescribed. Your healthcare provider will tell you when to take Brigalin. It is advised to take Brigalin at the same time each day.

How long to take it

Do not stop taking Brigalin without checking with your healthcare provider. If you stop taking Brigalin suddenly, you may have trouble sleeping, nausea, headaches, anxiety, excessive sweating, and diarrhea. If you have epilepsy and you stop taking Brigalin suddenly, you may have seizures more often.

If Brigalin is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly. Talk with your healthcare provider about how to stop Brigalin slowly.

If you forget to take it

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same time.

If you take too much

If you take too much Brigalin, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

These side effects were reported when Brigalin was taken too much:

Affective disorder (abnormal disturbances of mood), sleepiness, confusion, depression, agitation and restlessness.

Fits (seizures) were also reported when the medicine was taken in overdose.

While you are using it

Things you must do

Stop taking Brigalin and call your doctors or pharmacist immediately if you have any of these signs of serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck

- Trouble breathing
- Rash, hives (raised bumps) or blisters.

Call your doctor or pharmacist immediately if you have any of these symptoms, especially if they are new, worse or worry you:

- Thought about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

Things you must not do

Do not drive a car, work with machines, or do other dangerous activities until you know how Brigalin affect you.

Pregabalin may cause dizziness and extreme sleepiness which may impair the ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population.

Ask your healthcare provider about when it will be okay to do these activities.

Things to be careful of

If you have suicidal thoughts or actions, do not stop Brigalin without first talking to a doctor or pharmacist.

- Stopping Brigalin suddenly can cause serious problems.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Side Effects

Very Common:

- Dizziness, sleepiness
- Headache

Common:

- Cold
- Increased appetite
- Elevated mood, confused state, irritability, depression, loss in sense of direction, inability to sleep, reduced sex drive
- Lack of voluntary coordination of muscle, loss in control of posture, muscle contraction, loss of memory, memory impairment, disturbance in attention, abnormal tingling and pricking sensation, reduced sense of touch, relaxed state/reduction of irritability or agitation, balance disorder, lack of energy
- Blurry vision and double vision
- Loss of balance
- Vomiting, constipation or hard bowels, accumulation of gas in alimentary canal, accumulation of gas or air in the abdomen, dry mouth
- Muscle cramp, joint pain, back pain, pain in the limbs, tightening of muscles
- Accumulation of fluid in tissues, abnormal walking, fall, feeling drunk, feeling abnormal, weakness
- Increased weight
- Diarrhea, vomiting

Rare:

- Stevens-Johnson syndrome

If you have diabetes, you should pay attention to your skin while taking Brigalin and tell your healthcare provider about any sores or skin problems.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of Brigalin. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my. [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Brigalin

Storage

Store below 30 °C. Protect from light and moisture.

Keep out of the reach of the children.

Do not use this medicine after the expiry date.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Product Description

What it looks like

Brigalin Capsule 75mg:

Size 3, red/white hard gelatin capsule, printed with “XS” and “75”, filled with white to off-white granules.

Brigalin Capsule 150mg:

Size 2, white/white hard gelatin capsule, printed with “XS” and “150”, filled with white to off-white granules.

Ingredients

Active ingredient: Pregabalin.

Inactive ingredients: Maize Starch, Lactose Monohydrate, Purified Talc and hard gelatin capsule.

MAL Number

Brigalin Capsule 75mg:

MAL24056091AZ

Brigalin Capsule 150mg:

MAL24056090AZ

Manufacturer and Product

Registration Holder

Xepa-Soul Pattinson (Malaysia) Sdn Bhd
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