

SIRANALEN

Pregabalin 75mg, 150mg

What is in this leaflet

1. What Siranalen is used for
2. How it works
3. Before you use Siranalen
4. How to use Siranalen
5. While you are using it
6. Side effects
7. Storage and Disposal of Siranalen
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision
11. Serial number

What Siranalen is used for

Siranalen 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 generalisation
- 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 Siranalen works

Siranalen helps decrease the number of nerve signals, and as a result calms down overly sensitive nerve cells.

Before you use Siranalen

- When you must not use it

Do not take Siranalen if you:

- are allergic to pregabalin or any of the other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Tell your healthcare provider about all your medical conditions including if you:

- Have or had depression, mood problems or suicidal thoughts or behavior
- Have kidney problems or get kidney dialysis
- Have heart problems including heart failure
- Have a bleeding problem or a low blood platelet count
- Have abused prescription medicines, or street drugs in the past
- Have ever had swelling in your face, mouth (tongue, lips, gums) and neck (throat and larynx; angioedema)
- Are in the first trimester of

pregnancy as Siranalen 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.

Pregnancy and breast-feeding

Pregabalin may cause reproductive toxicity. Hence it should not be taken during pregnancy unless clearly necessary. Effective contraception must be used in women of childbearing potential.

Pregabalin is excreted in the milk of lactating women. As the safety of pregabalin in infants is not known, breast-feeding is not recommended during treatment with Siranalen. You and your healthcare providers should discuss whether you should take Siranalen or breast-feed, but you should not do both.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins or herbal supplements. Siranalen 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 Siranalen.
- 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 Siranalen.
- Any medicines that make you sleepy.
- Siranalen may increase the effects of

ethanol and lorazepam.

- Siranalen 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 Siranalen 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 Siranalen

- How much to use

The dose range is 150mg to 600mg per day given in either two or three divided doses.

Your healthcare provider may change your dose if you have kidney problem.

- When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Siranalen is for oral use. You may take it with or without food.

- How long to use it

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

If Siranalen 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 Siranalen slowly.

- If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of Siranalen that has been prescribed for you in one day.

- If you use too much (overdose)

Call your doctor or pharmacist

SIRANALEN

Pregabalin 75mg, 150mg

immediately if you take more than the amount of Siranalen prescribed by your doctor.

Symptoms of overdose include sleepiness, confusion, agitated and seizures.

While you are using it

- Things you must do

Stop taking Siranalen and call your healthcare provider immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Trouble breathing
- Rash, hives (raised bumps) or blisters

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

- Thoughts 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 stop taking your capsules without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Siranalen, he or she will ask you to reduce your dose over a week time.

- Things to be careful of

If you are suicidal thoughts or actions, do not stop Siranalen without first talking to your doctor. Stopping Siranalen suddenly can cause serious problems.

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.

Driving and using machines

Siranalen can make you dizzy and sleepy. Don't drive or use machines if you do not feel well.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 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 Siranalen and tell your healthcare provider about any sores or skin problems.

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

Storage and Disposal of Siranalen

- Storage

Keep this medicine out of sight and reach of children.

Store below 30°C in the original package.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

- What it looks like

Siranalen 75mg hard capsules: Blue-white hard gelatin capsules size "4" filled with off white powder

Siranalen 150mg hard capsules: White-white hard gelatin capsules size "2" filled with off white powder

Siranalen hard capsules are available in carton boxes with blister strips containing 100 capsules.

- Ingredients

- Active ingredient

The active substance is pregabalin.

- Inactive ingredient

Capsule content:

Maize starch, lactose monohydrate, talc

Capsule shell:

Capsule body: Gelatine, titanium dioxide (E171), Sodium lauryl sulfate, purified water

Capsule cap of 75mg: Gelatin (source from bovine), Titanium dioxide (E171), Patent blue V (E131), Sodium lauryl sulfate

- Capsule cap of 150mg: Gelatin (source from bovine), Titanium dioxide (E171), sodium lauryl sulfate

- MAL number:

Siranalen 75mg hard capsules: MAL24066024AZ

Siranalen 150mg hard capsules: MAL24066025AZ

Manufacturer

Medochemie Ltd (Far East Oral Facility),
40 Street 6, Vietnam Singapore
Industrial Park II, Binh Duong Industry
Service Urban Complex, Hoa Phu
Ward, Thu Dau Mot City, Vietnam

SIRANALEN

Pregabalin 75mg, 150mg

Product registration holder

Komedic Sdn Bhd,
4 Jalan PJS 11/14, Bandar Sunway,
46150 Petaling Jaya, Selangor D.E.

Date of revision

19/12/2024

Serial Number

NPRA(R2)23/112