

APPROVED PATIENT INFORMATION LEAFLET

S3

BINRONTIN 100 mg CAPSULES (capsule)

BINRONTIN 300 mg CAPSULES (capsule)

BINRONTIN 400 mg CAPSULES (capsule)

Gabapentin

Sugar free

Read all of this leaflet carefully before you start taking BINRONTIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BINRONTIN** 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

- What **[PRODUCT NAME]** is and what it is used for
- What you need to know before you take **[PRODUCT NAME]**
- How to take **[PRODUCT NAME]**
- Possible side effects
- How to store **[PRODUCT NAME]**
- Contents of the pack and other information

1. WHAT BINRONTIN CAPSULES IS AND WHAT IS IT USED FOR:

BINRONTIN CAPSULES is used to treat various forms of epilepsy. Your doctor will prescribe **BINRONTIN CAPSULES** if your current treatment is no longer fully controlling your epilepsy. You should take **BINRONTIN CAPSULES** in addition to your current treatment. If your doctor considers that it is necessary, **BINRONTIN CAPSULES** can also be used on its own.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BINRONTIN CAPSULES:

Do not take BINRONTIN CAPSULES:

- If you are sensitive to gabapentin and the other ingredients of **BINRONTIN CAPSULES**.
- If you are under the age of 12 years.
- If you are pregnant or breastfeeding your infant (see pregnancy and breastfeeding).
- If you have kidney problems.

Warnings and precautions

Take special care with BINRONTIN CAPSULES:

- If you realise that you are becoming depressed or if any existing depression worsens.
- **BINRONTIN CAPSULES** may affect your alertness and therefore caution should be exercised when driving a vehicle, operating machinery or performing hazardous tasks. Using alcohol together with **BINRONTIN CAPSULES** will intensify these effects.
- A small number of people being treated with anti-epileptics such as **BINRONTIN CAPSULES** have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- If you develop inflammation of the pancreas while taking **BINRONTIN CAPSULES**, your treatment with **BINRONTIN CAPSULES** may be stopped.
- **BINRONTIN CAPSULES** should be used with special care if you have a history of psychotic illness (where a person is not in touch with reality and is experiencing situations that are not real, with accompanying anxiety and talking in a way that makes no sense).
- If you have a history of medicine or drug abuse and dependence, talk to your doctor before taking **BINRONTIN CAPSULES** as **BINRONTIN CAPSULES** can cause drug dependence.
- It should also be used with special care if you suffer from kidney problems.
- If you need to stop **BINRONTIN CAPSULES** suddenly or reduce your dose, your doctor should monitor you carefully. Withdrawal symptoms may occur shortly after stopping **BINRONTIN CAPSULES** Symptoms that may occur after stopping **BINRONTIN CAPSULES** include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise.

- **BINRONTIN CAPSULES** should not be used if you have mixed seizures, and is not considered effective against absences seizures. If seizures get more frequent while using **BINRONTIN CAPSULES** consult your doctor immediately.
- If they have to perform an analysis of proteins in your urine, warn them that you are taking **BINRONTIN CAPSULES** as some tests (Ames N Multistick G reactive strip test) are sensitive and can artificially alter the results (see Other medicines with **BINRONTIN CAPSULES**).
- If you have a history of developing a serious skin reaction (for e.g. severe cutaneous adverse reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis or drug rash with eosinophilia and systemic symptoms) with the use of **BINRONTIN CAPSULES**, treatment must not be restarted.

Children and adolescents

BINRONTIN CAPSULES should not be given to children below 12 years of age.

Taking other medicines with BINRONTIN CAPSULES:

- **BINRONTIN CAPSULES** does not interact with phenytoin, carbamazepine, phenobarbitone, primidone and valproic acid (other medicines for the treatment of epilepsy).
- **BINRONTIN CAPSULES** is not expected to interact with other medicines against epilepsy or your oral contraceptive pill.
- The absorption of **BINRONTIN CAPSULES** from the stomach may be reduced if you are taking any medicines used to treat an ulcer (antacids containing aluminum and magnesium) at the same time. It is therefore recommended that **BINRONTIN CAPSULES** is taken at the earliest two hours after taking an antacid.
- Alcohol and other central nervous system (CNS) depressants (such as tranquilisers) should not be taken with **BINRONTIN CAPSULES** as they may increase the CNS depressant effect such as increase in sleepiness.
- You should not take **BINRONTIN CAPSULES** with any CNS (central nervous system) depressants, including opioids if you are a frail patient, elderly or you have serious underlying respiratory disease as it may lead to respiratory depression, sedation, and death

- If you are taking any medicines containing morphine, please tell your doctor or pharmacist as morphine may increase the effect of **BINRONTIN CAPSULES**
- **BINRONTIN CAPSULES** may change the results of some laboratory tests. If you require a urine test tell your doctor or hospital that you are taking **BINRONTIN CAPSULES**.

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

Taking **BINRONTIN CAPSULES** with food and drink:

BINRONTIN CAPSULES can be taken with or without food

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, 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 **BINRONTIN CAPSULES**.

Pregnancy

You should not take **BINRONTIN CAPSULES** while you are pregnant.

The safety of taking **BINRONTIN CAPSULES** during pregnancy is not known.

Breastfeeding

You should not take **BINRONTIN CAPSULES** while you are breastfeeding.

BINRONTIN CAPSULES crosses the placenta. Withdrawal syndrome has been reported in newborns exposed to **BINRONTIN CAPSULES** during pregnancy. Newborns should be monitored carefully.

Driving and using machinery:

- **BINRONTIN CAPSULES** may make you feel sleepy.
- Do not drive or operate any tools or machinery until you know how **BINRONTIN CAPSULES** affects you.

3. HOW TO TAKE BINRONTIN CAPSULES:

Always take **BINRONTIN CAPSULES** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BINRONTIN CAPSULES** is too strong or too weak, talk to your doctor or pharmacist.

Adults and children over 12 years old:

Take the number of capsules as instructed by your doctor. The starting dose will generally be between 300 mg and 900 mg each day. Your doctor will build up your dose gradually. This may be done over three days or longer depending on your response to **BINRONTIN CAPSULES**. Thereafter, your dose may be increased further, usually 900 mg to 1 800 mg per day up to a maximum of 3 600 mg per day. Your doctor will tell you to take the dose in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children under 12 years old:

BINRONTIN CAPSULES is not recommended for use in children under 12 years old.

Elderly patients:

If you have impaired kidney function or are undergoing haemodialysis your doctor will decide if you require a reduced dosage and how much you should take.

If you take too much BINRONTIN CAPSULES:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take too much **BINRONTIN CAPSULES** you may experience one or more of the following symptoms: dizziness, double vision, difficulty in speaking, sleeplessness, sleepiness and mild diarrhoea.

If you forget to take BINRONTIN CAPSULES:

Always take **BINRONTIN CAPSULES** exactly as prescribed. If you forget to take **BINRONTIN CAPSULES**, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and continue with your regular dosing schedule.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking BINRONTIN CAPSULES:

If your medicine is stopped by your doctor or if you are required to take another medicine, it should be done gradually over at least one week. Your doctor will advise you on how to do this.

Do not stop **BINRONTIN CAPSULES** before talking to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

BINRONTIN CAPSULES can have side effects.

If any of the following happens, stop taking **BINRONTIN CAPSULES** and tell your doctor immediately or go to the casualty department at your nearest hospital:

You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing.

- You could also notice itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to **BINRONTIN CAPSULES**.
- You have blistering, peeling or bleeding of the skin around the lip, eyes, mouth, nose and genitals. You may also have flu-like symptoms and a high temperature. These could be signs of Stevens-Johnson syndrome.
- You get symptoms such as: yellowing of your skin or whites of your eyes, tiredness and fever. This may be due to inflammation of the liver or changes in the way your liver is working.
- You develop signs such as persistent stomach pain, feeling sick (nausea), and/or being sick (vomiting). This could be a sign of pancreatitis (inflammation of the pancreas).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BINRONTIN CAPSULES**. 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:

- Acute anxiety, hallucinations, sleeplessness or over excitement
- Decrease in white blood cells (signs of recurrent infections or fever)
- Reduced numbers of blood platelets. Symptoms may include bleeding or bruising more easily than normal (thrombocytopenia)
- Fast or irregular heartbeats, chest pain, faster heart beat
- Inflammation of pancreas. Symptoms may include severe upper stomach pain, often with nausea and vomiting
- Thoughts about killing or harming yourself
- Inflammation of liver, symptoms may include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- Decreased urinary output, swelling due to fluid retention, nausea, fatigue and shortness of breath
- A rash combined with systemic symptoms such as fever, night sweats, fatigue, cough, chest pain,
- swelling, weakness, confusion and coma

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- Tiredness, sleepiness, dizziness, difficulty controlling your muscles, trembling
- Viral infection, respiratory infection, pneumonia (serious lung infection. Symptoms may include fever, chills, shortness of breath, cough, phlegm and occasionally blood), urinary tract infection (symptoms may include strong, persistent urge to urinate, burning sensation when urinating, passing frequent, small amounts of urine, strong-smelling urine); inflammation of the ear or other infections
- Vertigo (dizziness or spinning feeling in your head)
- Double vision, lazy eye, involuntary eye movement

- Depression, frequent mood changes
- Muscle pain
- Swelling of the limbs due to water retention
- Increased appetite, loss of appetite
- Confusion, depression, emotional lability, nervousness, thinking abnormal, hostility, anxiety
- Difficulty in controlling movements, dizziness, sleepiness, loss of memory, coordination abnormal, difficulty in speaking, inability to fall asleep, headache, nystagmus (rapid, uncontrollable movements of the eyes), tremor (shaking), fits, hyperkinesias (disorder of children marked by hyperactivity and inability to concentrate), sensations such as paresthesia (tingling or pricking, "pins-and-needles" sensation), diminished capacity for physical sensation, especially of the skin, coordination abnormal, increased, decreased, or absent reflexes
- Amblyopia (lazy eye, reduced vision in one eye caused by abnormal visual development early in life), double vision
- Vertigo (spinning sensation)
- Widening of blood vessels, hypertension (high blood pressure. Symptoms may include severe headaches, nosebleed, fatigue or confusion, vision problems, chest pain, difficulty breathing, irregular heartbeat)
- Coughing, pharyngitis (sore throat and discomfort when swallowing), rhinitis (runny or blocked nose, sneezing, facial pressure or pain), dyspnoea (shortness of breath), bronchitis (inflammation of the lining of bronchial tubes, which carry air to and from the lungs. Symptoms may include cough, fatigue or generally feeling unwell, runny nose or post-nasal drip, chest pressure, headache, shortness of breath, sleeping difficulty, or sore throat)
- Abdominal pain, constipation, dental abnormalities, diarrhoea (loose stools), indigestion, mouth or throat dry, nausea and/or vomiting, gingivitis (common and mild form of gum disease that causes irritation, redness and swelling of your gingiva, the part of your gum around the base of your teeth), flatulence (excessive gas in the stomach or bowel)
- Acne, itching, rash, swelling of face, bruises
- Back pain, muscle pain, twitching, joint pain
- Impotence (difficulties with erection)

- Tiredness, fever, swelling of hands, ankles or feet, difficulty with walking, unusual weakness, pain, generally feeling unwell, flu-like symptoms (fever or feeling feverish/having chills, cough, shortness of breath or difficulty breathing, tiredness, sore throat, runny or stuffy nose, muscle pain or body aches, headache)
- Weight gain
- Abrasion, fracture, accidental injury

Less frequent:

- Headache, difficulty pronouncing words, memory loss, confusion, trouble falling asleep, twitching, sensation of tingling, nervousness
- Abnormal coordination
- Nausea and vomiting, heartburn, discomfort in the stomach, dryness of mouth or throat, constipation, diarrhoea, dental problems
- Runny nose, sore throat, coughing, chest infection
- Acne, small, flat red spots on skin
- Toxic epidermal necrolysis (extensive exfoliation of the outer layer of skin and inner layer of nose and mouth)
- Abnormal thinking
- Erection problems
- Back pain, fracture
- Widening of blood vessels
- Red or purple discolouration on the skin
- Viral infection
- Increased appetite, resulting in weight gain
- Fever
- Hyperglycaemia (increase in blood glucose levels. Symptoms may include increased thirst and/or hunger, blurred vision, frequent urination (peeing), headache)
- Hypoglycaemia (decrease in blood glucose levels. Symptoms may include an irregular or fast heartbeat, tiredness, pale skin, shakiness, anxiety, sweating, hunger, irritability)
- Agitation (state of anxiety or nervous excitement)
- Unusually reduced or slow body movement, mental impairment, loss of consciousness

- Respiratory depression (breathing disorder characterized by slow and ineffective breathing)
- Difficulty in swallowing
- Generalized oedema (swelling that may involve the face, trunk and limbs)
- Hyponatraemia (low sodium levels in the blood. Symptoms may include Muscle cramps or weakness, nausea and vomiting, lethargy, or low energy, headache and confusion, mental status changes, fits)
- Hallucinations (seeing, feeling or hearing things that are not there)
- Involuntary fidgeting and movement, dyskinesia (uncontrollable twitching, jerking or writhing movements), and dystonia (uncontrollable muscle spasms affecting the eyes, head, neck and body), spastic torticollis (disorder where the muscles of the neck contract uncontrollably, making the head turn into various postures) and myoclonus (sudden, involuntary muscle jerk, shake or spasm)
- Tinnitus (ringing sensation in the ears)
- Jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- Alopecia (hair loss)
- Urinary incontinence (loss of bladder control, varying from a slight loss of urine after sneezing, coughing or laughing, to complete inability to control urination)
- Breast hypertrophy (condition in which breasts grow so heavy that they cause problems), gynaecomastia (breast enlargement in men), sexual dysfunction (including changes in sex drive, delayed ejaculation and inability to achieve a sexual climax)
- Change in blood test results
- Myoclonus (infrequent muscle twitches, low magnesium or muscle fatigue)

If you are an elderly patient, you may be more sensitive to these adverse reactions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side effects reported for **BINRONTIN CAPSULES** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BINRONTIN CAPSULES**, please consult your doctor, pharmacist or other health care professional for advice

Reporting of side effects

If you get side effects, talk to your healthcare professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **BINRONTIN CAPSULES**

5. HOW TO STORE BINRONTIN CAPSULES:

Store all medicines out of the reach of children.

PVC / PVdc Blister:

Store at or below 25 °C. Keep blisters in the original carton until required for use.

HDPE Container:

Store at or below 25 °C. Keep well closed.

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

The active substance is gabapentin.

BINRONTIN 100 mg CAPSULES: Each capsule contains 100 mg gabapentin.

BINRONTIN 300 mg CAPSULES: Each capsule contains 300 mg gabapentin.

BINRONTIN 400 mg CAPSULES: Each capsule contains 400 mg gabapentin.

The other excipients in the formulations are maize starch and talc.

The capsule shell consists of gelatine, red iron oxide, sodium lauryl sulphate, titanium dioxide and yellow iron oxide.

What BINRONTIN CAPSULES looks like and contents of the pack:

BINRONTIN 100 mg CAPSULES: White / White size '3' hard gelatin capsules imprinted with 'D' on white cap and '02' on white body with black edible ink filled with white to off-white crystalline powder.

BINRONTIN 300 mg CAPSULES: Yellow / Yellow size '1' hard gelatin capsules imprinted with 'D' on yellow cap and '03' on yellow body with black edible ink filled with white to off-white crystalline powder.

BINRONTIN 400 mg CAPSULES: Orange / Orange size '0' hard gelatin capsules imprinted with 'D' on orange cap and '04' on orange body with black edible ink filled with white to off-white crystalline powder.

BINRONTIN 100 mg CAPSULES:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer or in clear 250 micron PVC coated blisters with 90 gsm PVdC and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 100 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

BINRONTIN 300 mg CAPSULES:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer or in clear 250 micron PVC coated blisters with 90 gsm PVdC and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 120 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

BINRONTIN 400 mg CAPSULES:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer or in clear 250 micron PVC coated blisters with 90 gsm PVdC and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 200 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

HOLDER OF THE CERTIFICATE OF REGISTRATION:

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