

RIVOPAM TABLET

Clonazepam (0.5mg/2mg)

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What RIVOPAM is used for

Rivopam is used to treat epilepsy in infants, children and adults. It lowers the number of fits (seizures) that you have.

Ask your doctor if you have any questions about why Rivopam Tablet has been prescribed for you.

How RIVOPAM works

Rivopam contains a medicine called clonazepam. This belongs to a group of medicines called 'benzodiazepines'.

Before you use RIVOPAM

- When you must not use it

Do not take Rivopam if you are allergic to:

- medicines containing clonazepam or other benzodiazepines
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the

face, lips or tongue, which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Rivopam if you have:

- respiratory depression (decreased rate of breathing)
- lung disease
- an addiction to alcohol.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

- Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.
- Tell your doctor if you are pregnant or plan to become pregnant.
- It is not known whether Rivopam is safe to use during pregnancy.
- Therefore, if there is a need to take Rivopam during pregnancy, your doctor will discuss the risks and benefits with you.
- Tell your doctor if you are breastfeeding or plan to breastfeed.
- Rivopam is not recommended for use during breastfeeding as it passes into the breast milk.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- lung problems

Your doctor may want to take special care if you have any of these conditions.

- Tell your doctor if you drink alcohol.
- Alcohol may change the effects of Rivopam and may even cause you to have epileptic fits.
- If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Rivopam.

You must tell your doctor if you have any suicidal thoughts.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Rivopam.

How to use RIVOPAM

- How much to use

0.5mg Tablet

Infants

1–2 tablets divided into 3 – 4 doses over the day.

Children

2 – 5 years

3-6 tablets divided into 3 – 4 doses over the day.

6 – 12 years

6-12 tablets divided into 3 – 4 doses over the day.

Adult

8-16 tablet divided into 3 – 4 tablets over the day.

2mg Tablet

Infants

¼ - ½ tablet divided into 3 – 4 doses over the day.

Children

2 – 5 years

¾ - 1 ½ tablets divided into 3 – 4 doses over the day.

6 – 12 years

1 ½ - 3 tablets divided into 3 – 4 doses over the day.

Adult

2 - 4 tablets divided into 3 – 4 tablets over the day.

- When to use it

Swallow the tablets with a glass of water.

Depending on your dose, your doctor may recommend you take it three or four times a day.

Rivopam can be taken with or without food.

Take Rivopam at about the same time each day.

- How long to use it

Keep taking Rivopam for as long as your doctor recommends.

Rivopam helps to control your condition but does not cure it, so it is important to take it every day.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Rivopam Tablet.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose include drowsiness and uncoordinated movement.

While you are using it

- Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Rivopam.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rivopam.

If you become pregnant while taking Rivopam, tell your doctor immediately.

Tell your doctor if you feel that Rivopam is not helping your condition.

If you continue to have seizures (fits) your doctor may need to adjust or review your treatment.

Tell your doctor if, for any reason, you have not taken Rivopam exactly as prescribed.

Visit your doctor regularly so that they can check your progress.

- Things you must not do

Do not drink alcohol while you are taking Rivopam.

Alcohol can also affect how well Rivopam works and may even cause more seizures (fits).

Rivopam may cause drowsiness, dizziness or affect alertness in some people. These effects may continue the following day.

Therefore, make sure you know how Rivopam affects you before you drive a car, operate machinery or do anything else that could be dangerous.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Do not take Rivopam for a longer time than your doctor has prescribed.

Do not stop taking Rivopam or change the dose without first checking with your doctor.

Stopping this medicine suddenly may make your epilepsy worse and cause some unwanted effects. Your doctor will tell you how to gradually reduce the amount of Rivopam you are taking before stopping completely.

Do not let yourself run out of Rivopam over the weekend or on holidays.

Do not use Rivopam to treat any other conditions unless your doctor tells you to.

Do not give Rivopam to anyone else, even if they have the same condition as you.

- Things to be careful of

If Rivopam is being given to a small child, you should be especially careful that they are breathing freely.

Rivopam may increase the amount of saliva and fluid in the airways.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rivopam.

Rivopam helps most people with their epilepsy, but it may have unwanted side effects in some people.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, light headedness
- unsteadiness when walking
- muscle weakness
- slurred speech
- loss of memory, inattentiveness, confusion, lack of concentration, slowed reactions
- increased saliva secretion
- chest congestion
- headaches

Tell your doctor immediately if you notice any of the following:

- behaviour changes such as aggression, agitation, irritability, depression, restlessness.
- severe sleep disturbances,
- hallucinations or delusions
- bleeding or bruising more easily than normal
- nausea, constipation, dry mouth, coated tongue, abnormal thirst, sore gums.

The above list includes serious side effects which may require medical attention. Some of these side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, throat or neck, which may cause difficulty swallowing or breathing
- fainting
- more fits than usual
- difficulty breathing, shortness of breath

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers-->Reporting)

Storage and Disposal of RIVOPAM

- Storage

Store below 25°C. Protect from light.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Rivopam Tablet where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking Rivopam Tablet or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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

• **Rivopam Tablet 0.5mg**

A white 7 mm round tablet with marking 'd' and a 'flower'.

• **Rivopam Tablet 2mg**

A white 7 mm round tablet with marking 'DUO 861' and 'd'.

- Ingredients

Active Ingredient :

Each Rivopam Tablet 0.5mg contains 0.5mg of clonazepam

Each Rivopam Tablet 2mg contains 2mg of clonazepam

Inactive Ingredients :

- Cornstarch
- Magnesium Stearate
- PVP
- Talcum
- Promigel
- Tween 80
- Lactose

- MAL number

Rivopam Tablet 0.5mg:

MAL19950145A

Rivopam Tablet 2mg:

MAL19950146A

Manufacturer

DUOPHARMA (M) SDN.
BHD. (42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Product Registration Holder

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Date of Revision

09/12/2014

Serial Number

BPFK(R4/1)091214/00078