

BROMOCRIPTIN-RICHTER TABLET

Bromocriptine (2.5 mg)

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What *Bromocriptin-Richter* is used for

- Treating fertility and period problems usually caused by not having the right amount of prolactin. This includes polycystic ovary syndrome (reduces prolactin levels), medication induced excessive amount of prolactin.
- Treating non-cancerous tumours in the brain called prolactinomas (reduces prolactin levels).
- Treating diseases where too much growth hormone is made, which causes people to be very tall or to have large hands and feet. This is called acromegaly (reduces growth hormone levels)
- Treating Parkinson's disease (increases dopamine levels).

Ask your doctor if you have any questions about why *Bromocriptin-Richter* has been prescribed to you. Your doctor may have prescribed *Bromocriptin-Richter* for another reason.

How *Bromocriptin-Richter* works

Bromocriptine belongs to a group of medicines called dopamine agonists and prolactin inhibitor. It works by increasing the release of dopamine in the brain, which treats diseases where you need more of this substance. It also works by decreasing the release of prolactin and growth hormone in the body, which treats diseases where you need less of these substances.

Before you use *Bromocriptin-Richter*

- When you must not use it

Do not take *Bromocriptin-Richter* if you are allergic to:

- medicines containing bromocriptine
- ergot alkaloids, which are medicines usually used to treat migraine headaches
- 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 *Bromocriptin-Richter* if you have or have had any of the following medical conditions:

- essential and familial tremor
- Huntington's chorea
- severe heart disease
- mental illness
- high blood pressure that is not controlled
- pregnancy induced toxemia, a condition of blood pressure problems during pregnancy or after giving birth

Pregnancy and lactation

Do not take *Bromocriptin-Richter* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Bromocriptin-Richter* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Pediatric use: Safety and efficacy have not been established in children under the age of 15 years.

- Before you start to use it

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

- acromegaly (extremely rare condition where body produces excess growth hormone)
- stomach or intestinal bleeding

- psychotic disorders (severe mental disorders that cause abnormal thinking and perceptions)
- severe heart disease
- hyperprolactinemia (a condition of elevated serum prolactin)
- Parkinson's disease
- cancer disease
- hypertension (high blood pressure)
- liver or kidney disease
- pleural effusion (excess fluid that accumulate in lung)

- Taking other medicines

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

It can be given carefully with the following drugs:

- erythromycin, medicine used for infection
- dopamine antagonists, e.g. butyrophenons and phenothiazines

Concurrent use should be avoided:

- ergot-alkaloid derivatives (medicines used to treat migraine headaches)

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to use *Bromocriptin-Richter*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Menstrual cycle disorders and female infertility: 2.5-3.75 mg daily (half a tablet 2 or 3 times a day). If necessary the dose can be increased to 1 tablet 2 or 3 times daily. Treatment is continued until the menstrual cycle returns to

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normal and/or ovulation is restored. If required, treatment may be continued over several cycles to prevent relapse.

Prolactinomas: 2.5-3.75 mg daily (half a tablet 2 or 3 times a day), gradually increasing to several tablets daily as required to keep plasma prolactin adequately suppressed.

Acromegaly: Initially 2.5-3.75 mg daily (half a tablet 2 or 3 times a day), gradually increasing to 4 to 8 tablets (10-20 mg) daily depending on clinical response and side effects.

Benign breast disease: 2.5-3.75 mg daily (half a tablet 2 or 3 times a day), gradually increasing to 2 to 3 tablets per day.

Parkinson's disease: Treatment should be started with a low dose of 1.25 mg (half a tablet) given preferably in the evening, over the first week.

The increase of daily dosage should be gradual by increments of 1.25 mg a day every week.

The daily dosage is divided into two or three single doses. An adequate therapeutic response may be reached within 6 to 8 weeks.

The common therapeutic range for monotherapy or combined therapy is 10-40 mg bromocriptine per day. In some patients higher doses may be required, this should be considered individually. It is important to maintain optimal therapeutic response as long as possible with the minimal effective dose. Should undesirable reaction occur during the titration phase, the daily dose is to be reduced and maintained constant for at least a week. If the adverse reactions disappear the dose can be increased again. For safety reasons the maximal daily dose cannot be higher than 100 mg.

- When to use it

Use as directed by your doctor or pharmacist. *Bromocriptin-Richter* should always be taken with food.

- How long to use it

Continue taking *Bromocriptin-Richter* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Bromocriptin-Richter*.

Tell your doctor immediately if you become pregnant while taking this medication.

Your doctor may recommend annual gynaecological examinations (or every 6 months for postmenopausal women) and your blood pressure should be monitored periodically.

In case of parkinsonian patients, liver-kidney and hematopoietic functions should be regularly checked.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Bromocriptin-Richter* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful when drinking alcohol while taking Bromocriptine

Driving and using machines

Be careful driving or operating machinery or doing jobs that require you to be alert until you know how Bromocriptine affects you.

It can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning.

If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Like all medicines, *Bromocriptin-Richter* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Side effects during early treatment may include:

- nausea
- vomiting
- dizziness
- fatigue
- feeling dizzy or lightheaded after standing

Side effects during high dose treatment may include:

- hallucinations
- confusion
- visual disturbance
- dyskinesia (movement disorder)
- dryness of the mouth
- constipation
- leg cramps (can be controlled by reducing the dose)

If any of these side effects gets serious, or if you notice any side effects not listed

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in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with this medicine.

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

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 *Bromocriptin-Richter*

- Storage
Keep out of the reach and sight of children.

Store below 25°C, protected from light.

Do not store any medicine in the bathroom, or near a sink, or on a window sill. Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of the month.

- 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
Almost white, round, flat-faced bevel-edged bisect tablet of about 7 mm with an inscription of '2.5' on the plain side.

- Ingredients
Active ingredient:
2.5 mg bromocriptine as 2.87 mg bromocriptine mesilate in each tablet.

Inactive ingredients:
Silica colloidal anhydrous, magnesium stearate, talc, povidone, maize starch, microcrystalline cellulose, lactose monohydrate (41.0 mg)

- MAL number:
MAL19900673AZ

Manufacturer
Gedeon Richter Plc.
H-1103 Budapest
Gyömrői út 19-21
Hungary

Product Registration Holder
Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai
5 ½ Mile off Jalan Meru
41050 Klang, Selangor
Malaysia

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