

Apo-Bromocriptine

bromocriptine mesylate

2.5mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Bromocriptine.

This leaflet answers some common questions about Apo-Bromocriptine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apo-Bromocriptine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Bromocriptine is used for

The name of your medicine is Apo-Bromocriptine tablet. It contains the active ingredient bromocriptine (as bromocriptine mesylate).

Apo-Bromocriptine is used for:

- prolactin dependent menstrual cycle disorders (amenorrhoea, oligomenorrhoea, galactorrhoea)
- hyperprolactinaemia in man
- prolactinomas
- acromegaly
- inhibition of lactation
- Parkinson's disease

Your doctor may have prescribed Apo-Bromocriptine for another reason.

Ask your doctor if you have any questions about why Apo-Bromocriptine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Apo-Bromocriptine should not be administered to children.

Before you use Apo-Bromocriptine

When you must not use it

Do not use Apo-Bromocriptine if:

- **You are hypersensitive to, or have had an allergic reaction to bromocriptine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **You have the following health/medical conditions:**
 - hypersensitivity to ergot alkaloids
 - uncontrolled hypertension, hypertensive disorders of pregnancy, hypertension postpartum and in puerperium
 - coronary artery disease and other severe cardiovascular conditions
 - symptoms and/or history of serious psychiatric disorders
 - patients with pre-existing valve problems

- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Bromocriptine, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- hypertension
- a history of dementia or other psychiatric disorders
- peptic ulcer
- unexplained pleuropulmonary disorders
- impulse control disorders (e.g. pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating)
- diabetes
- impaired renal function

3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.

Bromocriptine inhibits lactation and should not be used by women who elect to breast-feed.

If you have not told your doctor about any of the above, tell them before you start using Apo-Bromocriptine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Bromocriptine.

Some medicines may interfere with Apo-Bromocriptine. These include:

- erythromycin or other macrolides or octreotide
- butyrophenones
- phenothiazines
- tricyclic antidepressants
- reserpine
- metoclopramide
- methyl dopa
- pimozide
- oestrogens
- TRF
- levodopa
- clonidine
- pargyline
- iproniazid
- anti-hypertensive agents
- ergot alkaloids

These medicines may be affected by Apo-Bromocriptine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with bromocriptine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Bromocriptine.

How to use Apo-Bromocriptine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read

How much to take

Menstrual cycle disorders, Galactorrhea, Female infertility:

Usual therapeutic dosage is 5 to 7.5mg daily in divided doses, but may range from 2.5mg to 30mg daily. Initial doses should be low (1.25 to 2.5mg) and slowly increased at 5 to 7 day intervals, as tolerated. The lowest dose possible, that controls symptoms, should be used. Treatment is continued until menstruation and/or ovulation has normalised.

Male hypogonadism:

Initial dosage 1.25mg 2 or 3 times a day gradually increasing to 5-10mg a day.

Prolactinomas:

1.25mg 2 or 3 times daily; this can be gradually increased as needed to suppress prolactin secretion.

Acromegaly:

Initially 1.25mg 2 or 3 times a day gradually increasing to 10-20mg a day, depending on side effects and clinical response.

Inhibition of lactation:

On day one take 1.25mg morning and night with food, increasing on day two to 2.5 mg twice daily. Therapy should be continued for 14 days to prevent rebound lactation. Treatment should be started as soon as possible after parturition or abortion.

Parkinson's Disease:

Starting doses must be low initially (1.25mg daily), preferably at bedtime, and dosage increases must be gradual e.g. at intervals of 5 to 7 days. Dosages should be individually titrated according to therapeutic response and tolerability and given in 2 to 3 divided doses. If an undesirable reaction occurs, the dosage should be reduced

for at least a week. Titration upwards may then be cautiously re-tried. An adequate therapeutic response may be reached in 6 to 8 weeks. When bromocriptine is added to regimens of levodopa where patients are experiencing motor difficulties or side-effects, it is recommended that the dose of levodopa is reduced prior to the addition of bromocriptine. As the dosage of bromocriptine is titrated upwards, the dose of levodopa may be reduced further.

Hepatic dysfunction:

Dosage may have to be reduced in patients with impaired hepatic function.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet(s) with a glass of water. Apo-Bromocriptine tablets should always be taken with food.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will advise you when you can stop taking Apo-Bromocriptine completely.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

While you are using Apo-Bromocriptine

Things you must do

Immediately stop taking Apo-Bromocriptine and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Bromocriptine.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Bromocriptine.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Bromocriptine.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Bromocriptine to last weekends and holidays.

Things you must not do

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

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Do not take any other medicine while you are taking Apo-Bromocriptine without first telling your doctor.

Do not take Apo-Bromocriptine for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Bromocriptine affects you.

Dizziness and fainting may occur during initiation of treatment with bromocriptine and may impair their ability to drive a car or operate machinery. Patients driving vehicles or operating machinery should exercise caution until they have determined their reaction to the drug.

Alcohol may decrease tolerability to bromocriptine.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Bromocriptine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much bromocriptine, it may cause nausea, vomiting, dizziness, postural hypotension, sweating, drowsiness and hallucinations.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Bromocriptine or if you have any questions or concerns.

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 adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

This list includes the most common side effects. Mostly, these are mild and transient:

- headache
- drowsiness
- nausea
- constipation

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

These may be serious side effects. You may need medical attention.

- Dizziness, Dyskinesia
- Somnolence, Paresthesia
- Excess daytime somnolence and sudden sleep onset
- Confusion, Psychomotor agitation, Hallucinations
- Psychotic disorders, Insomnia
- Vomiting, Dry mouth
- Diarrhoea, Abdominal pain, Retroperitoneal fibrosis, Gastrointestinal ulcer, Gastrointestinal haemorrhage
- Hypotension including orthostatic hypotension (which may in very rare instances lead to collapse)
- Reversible pallor of fingers and toes induced by cold (especially in patients who have a history of Raynaud's phenomenon)
- Tachycardia, Bradycardia, Arrhythmia
- Cardiac valvulopathy (including regurgitation) and related disorders (pericarditis and pericardial effusion)
- Pleural effusion, Pleural and pulmonary fibrosis, Pleuritis
- Dyspnoea
- Leg cramps
- Allergic skin reactions, hair loss
- Fatigue
- Peripheral oedema
- A syndrome resembling Neuroleptic Malignant Syndrome has been reported on withdrawal of bromocriptine.
- Visual disturbances, vision blurred
- Tinnitus

Post-partum women

In extremely rare cases (in postpartum women treated with bromocriptine for the prevention of lactation) serious adverse events including hypertension, myocardial infarction, convulsion, stroke or mental disorders have been reported, although the causal relationship is uncertain. In some patients the occurrence of convulsion or stroke was preceded by severe headache and/or transient visual disturbances.

Impulse control disorders

Pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists including bromocriptine.

If you or someone you know or care for experience any of the following, stop taking bromocriptine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using Apo-Bromocriptine

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from heat, light and moisture.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

Apo-Bromocriptine 2.5mg tablets are white, oval, slope-faced & flat-faced tablets with bevelled edges. Scored and engraved APO 2.5 on slope side, plain on flat side.

Apo-Bromocriptine 2.5mg tablets are available in bottles of 30 and 100 tablets*.

* Not all pack sizes may be available.

Ingredients

Active ingredient:

Each tablet contains 2.5mg bromocriptine (as bromocriptine mesylate).

Inactive ingredients:

- Croscarmellose sodium
- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose

This medicine is gluten free.

This medicine contains lactose.

Sponsor Details

Apo-Bromocriptine is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Glenfield
AUCKLAND 0627

Telephone: (09) 444 2073

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