1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN-BROMOCRIPTINE 2,5 mg tablets

Bromocriptine

Contains sugar: Lactose monohydrate 70,133 mg

Read all of this leaflet carefully before you start taking ASPEN-BROMOCRIPTINE 2,5 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ASPEN-BROMOCRIPTINE 2,5 mg 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

1. What ASPEN-BROMOCRIPTINE 2,5 mg is and what it is used for
2. What you need to know before you take ASPEN-BROMOCRIPTINE 2,5 mg
3. How to take ASPEN-BROMOCRIPTINE 2,5 mg
4. Possible side effects
5. How to store ASPEN-BROMOCRIPTINE 2,5 mg
6. Contents of the pack and other information

1. What ASPEN-BROMOCRIPTINE 2,5 mg is and what it is used for

ASPEN-BROMOCRIPTINE 2,5 mg belongs to a group of medicines called dopamine agonists and prolactin inhibitors.

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.

Stopping breast milk production for medical reasons only, and when you and your doctor have decided that it is necessary. ASPEN- BROMOCRIPTINE 2,5 mg should not routinely be used to stop breast milk production. It should also not be used to relieve symptoms of painful breast engorgement after giving birth if these can be adequately treated with non-medical means (such as firm breast support, ice application) and/or a painkiller.
Treating fertility and period problems usually caused by not having the right amount of prolactin. This includes polycystic ovary syndrome (reduces prolactin levels).
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).

2. What you need to know before you take ASPEN-BROMOCRIPTINE 2,5 mg

Do not take ASPEN BROMOCRIPTINE 2,5 mg:

- if you are hypersensitive (allergic) to bromocriptine mesilate or other ergot alkaloids such as ergotamine or any of the other ingredients of ASPEN BROMOCRIPTINE 2,5 mg (listed in section 6).
- if you have high blood pressure.

- if you have ever had blood pressure problems during pregnancy or after giving birth, such as eclampsia, pre-eclampsia, pregnancy-induced high blood pressure, high blood pressure after giving birth.
- if you have, or have ever had, heart disease, or other severe blood vessel disease.
- if you have, or have ever had, fibrotic reactions (scar tissue) affecting your heart.
- if you have, or have ever had, serious mental health problems.

Warnings and precautions

Take special care with ASPEN-BROMOCRIPTINE 2,5 mg

- if you have just given birth as you may be more at risk of certain conditions. These are very rare but may include high blood pressure, heart attack, convulsions, stroke or mental problems. Therefore, your doctor will need to check your blood pressure regularly during the first days of treatment. Speak immediately to your doctor if you experience high blood pressure, chest pain or unusually severe or persistent headache, with or without vision problems.
- if you have or have ever had stomach ulcers and bleeding.
- if you have liver disease.
- if you have or have ever had a condition called fibrosis. Fibrosis causes thickening and stiffening of the heart, lungs and abdomen which can stop them working properly. Before you are given ASPEN-BROMOCRIPTINE 2,5 mg your doctor will check that your heart, lungs and kidneys are in good condition. The doctor may also do an ultrasound (an echocardiogram) of your heart for check for scar tissue.
- if you are pregnant or planning to become pregnant. If so, tell your doctor immediately.
- if you have recently given birth, had a miscarriage or an abortion.
- if you have premenstrual problems or non-cancerous breast disease.
- if you have a non-cancerous tumour. You may need a full medical check-up first.

- if you have Parkinson's disease.

Children and adolescents

Do not give ASPEN-BROMOCRIPTINE 2,5 mg to children.

Other medicines and ASPEN-BROMOCRIPTINE 2,5 mg

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

Tell your doctor if you are taking any of the following:

- Any medicine used to change your blood pressure, such as diuretics ('water tablets'), beta-blockers, calcium channel blockers or ACE inhibitors.
- Ergot alkaloids such as ergometrine (used to stop blood loss after giving birth) and ergotamine tartrate (used to treat migraines). This is especially important if you have just given birth or had an abortion.
- Erythromycin or any other macrolide antibiotics (used to treat infections).
- Azole anti-fungals (used to treat fungal infections).
- Protease inhibitors (used to treat HIV).
- Octreotide (used to treat growth disorders).
- Antipsychotics such as phenothiazines, butyrophenones, thioxanthenes (used to treat mental disorders).
- Metoclopramide and domperidone (used to stop you feeling and being sick).
- Any other medicine, including medicines obtained without a prescription.

ASPEN-BROMOCRIPTINE 2,5 mg with food, drink and alcohol

You must take this medicine with a meal.

Avoid drinking alcohol as it may make the side effects of this medicine worse.

Pregnancy, breastfeeding and fertility

You should not take ASPEN-BROMOCRIPTINE 2,5 mg if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You must not breastfeed. This medicine stops or slows down your breasts making milk.

Remember: Taking this medicine may increase or bring back your chances of getting pregnant. If you do not wish to get pregnant, ask your doctor for advice.

Driving and using machines

ASPEN-BROMOCRIPTINE 2,5 mg has a major influence on the ability to drive and use machines.

You must not drive or operate machines if you feel dizzy or faint. This may mean you have low blood pressure.

This is most likely to happen in the first few days. You may also feel very tired or suddenly fall asleep during the day whilst taking this medicine; if this happens you should not drive.

It is not always possible to predict to what extent ASPEN-BROMOCRIPTINE 2,5 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ASPEN-BROMOCRIPTINE 2,5 mg affects them (see section 4).

ASPEN-BROMOCRIPTINE 2,5 mg contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ASPEN-BROMOCRIPTINE 2,5 mg

Do not share medicines prescribed for you with any other person.

Always take ASPEN-BROMOCRIPTINE 2,5 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Always take this medicine with a meal.

Your doctor will tell you how much to take.

Medical check-ups

When you are taking this medicine, your doctor may ask
you to come for check-ups which may include:

- An ultrasound of your heart (an echocardiogram). This is to ensure that your heart is working properly and to check for fibrotic reactions. If fibrotic reactions occur, your doctor may stop your treatment with ASPEN BROMOCRIPTINE 2,5 mg.
- Blood pressure checks. This is important when you first start to take this medicine.
- If you are a woman and you have been taking ASPEN-BROMOCRIPTINE 2,5 mg for a long time you may have six monthly gynaecological exams and cervical smear tests.
- Eye sight checks.
- If you are taking ASPEN-BROMOCRIPTINE 2,5 mg for a disease involving a tumour, the size, shape and type of tumour may be checked regularly.

Your doctor will tell you how long your treatment with ASPEN-BROMOCRIPTINE 2,5 mg will last. Do not stop treatment early. If you have the impression that the effect of ASPEN-BROMOCRIPTINE 2,5 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ASPEN-BROMOCRIPTINE 2,5 mg than you should

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

Do not take more ASPEN BROMOCRIPTINE 2,5 mg than you should. If you accidentally take too much of your medicine, immediately tell your doctor or go to the nearest hospital casualty department. Taking too much ASPEN-BROMOCRIPTINE 2,5 mg may make you feel or be sick, have a fever or become abnormally tired.

If you forget to take ASPEN-BROMOCRIPTINE 2,5 mg

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

If you have missed a dose of ASPEN-BROMOCRIPTINE 2,5 mg, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking ASPEN-BROMOCRIPTINE 2,5 mg

It is important to talk to your doctor if you want to stop taking your medicine. If you stop suddenly, you may get withdrawal symptoms including confusion, a reduced attention span and stiffness.

If you have any further questions about taking this medicine, ask your doctor or pharmacist.

4. Possible side effects

ASPEN-BROMOCRIPTINE 2,5 mg can have side effects.

Not all side effects reported for ASPEN-BROMOCRIPTINE 2,5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN-BROMOCRIPTINE 2,5 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking ASPEN-BROMOCRIPTINE 2,5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN-BROMOCRIPTINE 2,5 mg. 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:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing, shortness of breath, pain when you breath in, or a cough that doesn’t go away,

- if you have just given birth you may be more at risk of certain conditions that include high blood pressure, heart attack, or mental problems,
- convulsions (fitting),
- strokes,
- stomach bleeding in acromegaly patients.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, drowsiness,
- feeling and being sick,
- constipation,
- blocked nose.

Less frequent side effects:

- restlessness, confusion, hallucinations,
- dry mouth,
- dizziness or light-headedness upon standing which may cause you to collapse (you may have low blood pressure),
- leg cramps,
- hair loss,
- tiredness,
- extreme drowsiness,
- insomnia (trouble sleeping),
- pins and needles,
- mental health problems,

- diarrhoea,
- inability to pass water and back pain,
- swelling of the ankles,
- disturbed or blurred vision,
- watery discharge from your nose,
- ringing in your ears,
- extreme drowsiness during the day or falling asleep unexpectedly,
- pale or white fingers and toes, caused by cold temperatures,
- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - strong impulse to gamble excessively despite serious personal or family consequences,
  - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive,
  - uncontrollable excessive shopping or spending
    binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

Side effects with an unknown frequency:

- dopamine dysregulation syndrome (DDS). It typically occurs in people with Parkinson's disease (PD) who have taken dopamine agonist medications for an extended period of time,
- altered liver function tests.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ASPEN-BROMOCRIPTINE 2,5 mg.

5. How to store ASPEN-BROMOCRIPTINE 2,5 mg

Store all medicines out of reach of children.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- 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

What ASPEN-BROMOCRIPTINE 2,5 mg contains

The active substance is 2,5 mg of bromocriptine mg.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Contains sugar: Lactose monohydrate 70,133 mg.

What ASPEN-BROMOCRIPTINE 2,5 mg looks like and contents of the pack

ASPEN-BROMOCRIPTINE 2,5 mg is a white, oval-shaped, bevelled edged tablet, slope-faced towards a score line on one side, flat-faced and plain on the other side.

30, 90 or 100 tablets are packed in a clear amber round glass bottle with a white metal cap with permaseal liner and glossy coated pulp liner beneath, together with coiler rayon and a leaflet.

30, 90 or 100 tablets are packed in a white round high-density polyethylene bottle, with a white polypropylene cap with induction heat seal liner, together with rayon and either a polypropylene or high-density polyethylene desiccant disk or a silica gel bag. The bottle is packed into a unit carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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