1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DOXURRA 0,5 mg tablets

Cabergoline

Contains sugar: Lactose anhydrous 75,9 mg

Read all of this leaflet carefully before you start taking DOXURRA

- 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.
- DOXURRA 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 DOXURRA is and what it is used for

DOXURRA belongs to a group of medicines called dopamine agonists. Dopamine is produced naturally in the body and helps to transmit messages to the brain.

DOXURRA is used to:

- stop breast milk production (lactation) soon after childbirth, stillbirth, abortion or miscarriage. It can also be used if you do not want to continue to breastfeed your baby once you have started.
- treat other conditions caused by hormonal disturbance which can result in high levels of prolactin being produced. This includes lack of periods, infrequent and very light menstruation, periods in which ovulation does not occur and secretion of milk from your breast without breastfeeding. Also, in conditions in which high levels of prolactin are due to unknown causes (idiopathic hyperprolactinaemia) or are caused by tumours of the pituitary gland in both men and women.

2. What you need to know before you take DOXURRA

Do not take DOXURRA:

- if you are hypersensitive (allergic) to cabergoline, any ergot alkaloid (e.g. pergolide, bromocriptine, ergotamine) or any of the other ingredients of DOXURRA (listed in section 6),
- if you are pregnant or breastfeeding your baby. You should stop breastfeeding your baby once you start taking DOXURRA (see section Pregnancy, breastfeeding and fertility),
- if you had high blood pressure, swelling of the hands and feet or protein in your urine in the second half of your pregnancy or soon after you have given birth to your baby (pre-eclampsia or toxaemia of pregnancy, post-partum hypertension),

- if you have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs,
- if you have liver problems,
- if you are being treated with anti-psychotic medicines used to treat mental illnesses, or if you have a history of mental illness associated with childbirth (puerperal psychosis),
- if you will be treated with DOXURRA for a long time and have stiff and inflamed heart valves (cardiac valvulopathy).

Warnings and precautions

Take special care with DOXURRA:

- If you suffer from any of the following inflammatory disorders: inflammation of the linings around the lungs (pleuritis), build-up of fluid between the tissue that lines the lungs and the chest (pleural effusion), thickening and stiffening of the linings around the lungs (pleural fibrosis), a lung disease that occurs when lung tissue becomes damaged and scarred (pulmonary fibrosis), swelling and irritation of the thin, sac-like membrane surrounding the heart (pericarditis), the build-up of too much fluid in the double-layered, sac-like membrane around the heart (pericardial effusion), one or more of the valves in your heart doesn't work properly (cardiac valvulopathy involving one or more valves e.g. aortic, mitral and tricuspid) or a rare condition that occurs when excess fibrous tissue develops in the space behind your stomach and intestine (retroperitoneal fibrosis). Fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with DOXURRA for a long period, your doctor will check before starting treatment whether your heart, lungs and kidneys are in good condition. They will also have an echocardiogram (an ultrasound test of the heart) taken before treatment is started and at regular intervals during treatment. If fibrotic reactions occur treatment will have to be discontinued.

- if you have kidney problems,
- if you have a disease that involves the heart and blood vessels (cardiovascular disease),
- if you have a condition in which some areas of the body feel numb and cool in certain circumstances (Raynaud's syndrome),
- if you have a stomach ulcer or if you are bleeding from your stomach or intestines,
- if you have a history of a serious mental illness, particularly psychotic disorders,
- if you have low blood pressure or if you are taking any medicine that lowers your blood pressure,
- if, while taking DOXURRA, you suddenly fall asleep,
- if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These urges can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose,
- if you are on long-term treatment with DOXURRA for hormonal disorders, it is recommended that women should have regular gynaecological exams including smear tests and pregnancy tests. Your doctor will continue to monitor your medical condition while you are taking DOXURRA,
- if you are taking DOXURRA for a long time, your doctor will check before starting treatment whether your heart, lungs and kidneys are in good condition, whether your blood does not have a tendency to form clots and if you have any other infections. Your doctor will also have an echocardiogram (ECG) (an ultrasound test of the heart) done

before treatment is started and at regular intervals during treatment. If fibrotic reactions occur treatment will have to be discontinued,

- if during long-term treatment with DOXURRA, you develop difficulty in breathing, shortness of breath, cough or chest pain, difficulty in urinating, pain and swelling in your legs or ankles or heart problems, you should tell your doctor immediately.

Children and adolescents

The safety of DOXURRA has not been established in children younger than 16 years.

Other medicines and DOXURRA

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:

- Ergot derivatives (e.g. dihydroergotamine, ergotamine, bromocriptine, pergolide): dihydroergotamine and ergotamine are used to treat migraine; bromocriptine and pergolide are used to treat Parkinson's disease (see section Do not take DOXURRA).
- Anti-hypertensive medicines (e.g. enalapril, losartan etc.): medicine used to treat high blood pressure.
- Antipsychotic medicines (e.g., prochlorperazine, chlorpromazine, haloperidol, flupenthixol): medicines used to treat mental illnesses such as schizophrenia.
- Anti-nausea medicine (e.g., metoclopramide): medicine used to treat nausea and vomiting.
- Macrolide antibiotics (e.g. erythromycin): medicine used to treat bacterial infections.

DOXURRA with food

DOXURRA should preferably be taken with meals.

Pregnancy, breastfeeding and fertility

You should not take DOXURRA if you are pregnant or breastfeeding your baby.

DOXURRA will stop your breast milk production, so if you plan to breastfeed your baby, you should not take DOXURRA.

You should also take care not to become pregnant for at least one month once you have stopped taking DOXURRA. If you become pregnant during treatment with DOXURRA, stop taking DOXURRA and inform your doctor who will then monitor your pregnancy as DOXURRA can result in abnormalities in your baby if you use it during pregnancy.

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.

Driving and using machines

DOXURRA may cause dizziness, drowsiness, visual impairment and sudden sleepy episodes (in some cases without warning signs or awareness) which may influence your ability to drive, operate machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent DOXURRA 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 DOXURRA affects them (see section 4).

DOXURRA contains lactose anhydrous

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 DOXURRA

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

Always take DOXURRA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of DOXURRA:

- **To stop/prevent the production of milk:** You should take 1 mg (two 0,5 mg tablets) on the first day after giving birth to your baby.
- **To stop milk production once you have started to breastfeed:** You should take 0,25 mg (one half of DOXURRA 0,5 mg tablet) every 12 hours for two days.
- **To reduce the level of the hormone prolactin in other conditions**: You should initially take one 0,5 mg tablet (to be taken in one or two doses) spread out over a week (e.g., half a tablet on Monday and the other half of the tablet on Thursday). Your dose can be increased gradually until you respond to treatment.

DOXURRA should be taken preferably with meals.

Your doctor will tell you how long your treatment with DOXURRA will last. Do not stop treatment early because you may experience unwanted side effects. If you have the impression that the effect of DOXURRA is too strong or too weak, tell your doctor or pharmacist.

If you take more DOXURRA than you should

There is no experience in humans of overdosage with cabergoline, as in DOXURRA when you use it as you should (see “HOW TO TAKE” above). In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

You may experience nausea, vomiting, stomach complaints, low blood pressure when standing up or confusion if you take more DOXURRA than you should.

If you forget to take DOXURRA

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

If you have missed a dose of DOXURRA, 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.

4. Possible side effects

DOXURRA can have side effects.

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

If any of the following happens, stop taking DOXURRA 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 DOXURRA. 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:

- changes in the way your heart beats, for example if you notice it beating faster or irregularly, heart problems such as heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the sac around the heart (pericardial effusion). The early symptoms may be one or more of the following: difficulty breathing, shortness of breath, pounding heart, feeling faint, chest pain, back pain, pelvic pain or swollen legs. These may also be the first signs of a condition called pulmonary fibrosis, which can affect the lungs, heart/heart valves or lower back,
- chest pain (angina pectoris),
- fluid build-up in the lungs, causing difficulty in breathing (pleural effusion),
- abnormal liver function, which may cause yellowing of the skin and eyes (jaundice), abnormal tiredness or severe pain in the upper abdomen.

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:

- Feeling abnormally sad or down (depression),
- light-headedness and loss of balance (dizziness, vertigo), headache,
- feeling extremely sleepy (somnolence),
- sudden feeling of warmth or heat in the body (hot flushes),
- low blood pressure, which also happens when standing up (postural hypotension),
- abdominal pain, nausea, heartburn, indigestion (dyspepsia, gastritis), difficulty passing stool (constipation), vomiting,
- breast pain,
- lack of energy, weakness or loss of strength (asthenia, fatigue).

Less frequent side effects:

- Increased sexual drive (libido, hypersexuality),
- short periods of blindness over half the field of vision (transient hemianopsia, visual impairment),
- fainting or passing out (syncope),
- burning or prickling sensation (paresthesia),
- nosebleeds (epistaxis),
- pain or discomfort right below your ribs in the area of your upper abdomen (epigastric pain),
- hair loss (alopecia),
- leg cramps,
- fluid build-up in the hands, legs or face (oedema).

Side effects with an unknown frequency

- Aggression, abnormal or unusual thoughts (delusions), strong impulse to gamble excessively (pathological gambling), abnormal thinking and perceptions (psychotic disorder), seeing or hearing things that are not really there (hallucinations),
- sudden sleep onset,
- unintentional muscle movement involving to-and-fro movements (tremor),
- abnormal liver and abnormal blood tests of liver function (blood creatinine phosphokinase increased, liver function tests abnormal),
- medicine withdrawal symptoms such as lack of interest (apathy), anxiety, depression, tiredness (fatigue), sweating and pain.

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

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 DOXURRA.

5. How to store DOXURRA

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

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 DOXURRA contains

The active substance is 0,5 mg of cabergoline.

The other ingredients are lactose anhydrous and L-Leucine.

Contains sugar: Lactose anhydrous 75,9 mg

What DOXURRA looks like and contents of the pack

DOXURRA is a white to off-white, capsule shaped, flat, bevelled edge, uncoated tablet engraved with “43” on one side and score line on other side. The tablet can be divided into equal halves.

DOXURRA is packed into an amber glass bottle and sealed with a white, aluminium, roll on pilfer proof (ROPP) cap containing silica gel. The amber glass bottle is packed into an outer carton. Pack sizes of 2 or 4 tablets.

DOXURRA is packed into an HDPE bottle, with a silica gel canister and sealed with a PP screw cap with an induction wad. The HDPE bottle is packed into an outer carton. Pack sizes of 2 or 4 tablets.

Not all packs or pack sizes may be 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