AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS: S4

ACTAMASIN 25 (25 mg film coated tablet)

Exemestane

Contains sugar: Mannitol – 0.0904 mg

Read all of this leaflet carefully before you start taking ACTAMASIN 25

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACTAMASIN 25 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 ACTAMASIN 25 is and what it is used for
2. What you need to know before you use ACTAMASIN 25
3. How to take ACTAMASIN 25
4. Possible side effects
5. How to store ACTAMASIN 25
6. Contents of the pack and other information

1. What ACTAMASIN 25 is and what it is used for

Your medicine is called ACTAMASIN 25. ACTAMASIN 25 belongs to a group of medicines known as aromatase inhibitors. These medicines interfere with a substance called aromatase, which is needed to make the female sex hormones, oestrogens, especially in postmenopausal women. Reduction in oestrogen levels in the body is a way of treating hormone dependent breast cancer.
ACTAMASIN 25 is used to treat hormone dependent early breast cancer in postmenopausal women after they have completed 2 years of treatment with the medicine tamoxifen.

Initials:

ACTAMASIN 25 is also used to treat hormone dependent advanced breast cancer in postmenopausal women when a different hormonal medicine treatment has not worked well enough.

2. What you need to know before you use ACTAMASIN 25

Do not take ACTAMASIN 25:

- if you are or have previously been allergic to exemestane (the active ingredient in ACTAMASIN 25) or any of the other ingredients of this medicine (listed in section 6).
- if you have not already been through 'the menopause', i.e. you are still having your monthly period.
- if you are pregnant, likely to be pregnant or breast-feeding.

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before taking ACTAMASIN 25.
- Before treatment with ACTAMASIN 25, your doctor may want to take blood samples to make sure you have reached the menopause.
- Routine checking of your vitamin D level will also be made before treatment, as your level may be very low in the early stages of breast cancer. You will be given vitamin D supplement if your levels are below normal.
- Before taking ACTAMASIN 25, tell your doctor if you have problems with your liver or kidneys.
- Tell your doctor if you have a history or are suffering from any condition which affects the strength of your bones. Your doctor may want to measure your bone density before and during the treatment of ACTAMASIN 25. This is because medicines of this class lower the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength and increase your risk of breaking a bone.

Other medicines and ACTAMASIN 25:

Always tell your doctor or pharmacist if you are taking, any other medicines. This includes complementary or traditional medicines).

ACTAMASIN 25 should not be given at the same time as hormone replacement therapy (HRT).

The following medicines should be used cautiously when taking ACTAMASIN 25. Let your doctor know if you are taking medicines such as:

- rifampicin (an antibiotic used for the treatment of TB),
- carbamazepine or phenytoin (anticonvulsants used to treat epilepsy),
- the herbal remedy St John's Wort (Hypericum perforatum), or preparations containing it.

Taking ACTAMASIN 25 with food and drink:

The recommended dose is one 25 mg tablet daily taken with meals.

Pregnancy, breastfeeding and fertility:

Do not take ACTAMASIN 25 if you are pregnant or breast-feeding. If you are pregnant or think you might be, tell your doctor.

Discuss contraception with your doctor if there is any possibility that you may become pregnant.

Driving and using machinery:

If you feel drowsy, dizzy or weak whilst taking ACTAMASIN 25, you should not attempt to drive or operate machinery.

3. How to use ACTAMASIN 25

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

Adults and the elderly patients

Always take ACTAMASIN 25 exactly as your doctor has told you. Check with your doctor or your pharmacist if you are not sure.

ACTAMASIN 25 tablets should be taken by mouth after a meal at approximately the same time each day. Your doctor will tell you how to take ACTAMASIN 25 and for how long. *The recommended dose is one 25 mg tablet daily taken with meals*.

Do not stop treatment even if you are feeling well, unless your doctor tells you. If you have the impression that the effect of ACTAMASIN 25 is too strong or too weak, tell your doctor or pharmacist.

If you need to go to the hospital whilst taking ACTAMASIN 25, let the medical staff know what medication you are taking.

Use in children

ACTAMASIN 25 is not suitable for use in children.

If you take more ACTAMASIN 25 than you should:

If too many tablets are taken by accident, contact your doctor or pharmacist at once or go straight to the nearest hospital casualty department. Show them the pack of ACTAMASIN 25 tablets.

If you missed a dose of ACTAMASIN 25:

If you forget to take your tablet, take it as soon as you remember. If it is nearly time for the next dose, skip the dose and take only a single dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking ACTAMASIN 25:

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

ACTAMASIN 25 can cause side effects. Not all side effects reported for ACTAMASIN 25 are included in this leaflet. Should your general health worsen of if you experience any untoward effects while taking ACTAMASIN 25, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking / using ACTAMASIN 25 and tell your doctor, pharmacist or healthcare provider 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’,

These are all very serious side effects. If you have them, you may have had a serious reaction to ACTAMASIN 25. 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,

Hypersensitivity, inflammation of the liver (hepatitis) and inflammation of the bile ducts of the liver which cause yellowing of the skin (cholestatic hepatitis) may occur. Symptoms include feeling generally unwell, nausea, jaundice (yellowing of the skin and eyes), itching, right sided abdominal pain and loss of appetite. Contact your doctor promptly to seek urgent medical advice if you think you have any of these symptoms.

In general, ACTAMASIN 25 is well tolerated and the following side effects observed in patients treated with ACTAMASIN 25are mainly mild or moderate in nature. Most of the side effects are associated with a shortage of oestrogen (e.g. hot flushes).

Tell your doctor or pharmacist as soon as possible if you notice any of the following side effects:

Frequent side effects

- Depression
- Difficulty sleeping
- Headache
- Hot flushes
- Dizziness
- Feeling sick
- Increased sweating
- Muscle and joint pain (including osteoarthritis, back pain, arthritis and joint stiffness)
- Tiredness
- Abdominal pain
- Elevated level of liver enzymes
- Pain
- Abnormally low body weight (anorexia)
- Carpal tunnel syndrome (a combination of pins and needles, numbness and pain affecting all of the hand except the little finger) or tingling/prickling of the skin
- Vomiting (being sick), constipation, indigestion, diarrhoea
- Hair loss
- Skin rash, hives and itchiness

- Thinning of bones which might decrease their strength (osteoporosis), leading to bone fractures (breaks or cracks) in some cases
- Swollen hands and feet
- Feeling of weakness

Less frequent side effects

- Hypersensitivity
- A reduction in the number of white blood cells
- Elevated level of a blood enzyme in the blood due to liver damage
- Elevated level of a haemoglobin breakdown in the blood
- A reduction in the number of platelets in the blood
- A breakout of small blisters on an area of the skin in a rash
- Drowsiness
- Inflammation of the liver
- Inflammation of the bile ducts of the liver which cause yellowing of the skin

Frequency unknown

- Low level of certain white blood cells in the blood

Changes in the amount of certain blood cells (lymphocytes) and platelets circulating in your blood, especially in patients with a pre-existing lymphopenia (reduced lymphocytes in the blood) may also be seen.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of ACTAMASIN 25.

5. How to store ACTAMASIN 25

- Store all medicine out of reach of children.
- Store at or below 25 °C. Protect form light.

- Keep the blister in the outer carton until required for use.
- Do not use this medicine after the expiry date which is stated on the outer carton and the blister.

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 ACTAMASIN 25 contains

- The active substance is exemestane. Each coated tablet contains 25 mg exemestane.
- The other ingredients are: Colloidal anhydrous silica, crospovidone, hypromellose, macrogol, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate, sodium starch glycolate and titanium dioxide.
- What ACTAMASIN 25 looks like and contents of the pack

ACTAMASIN 25 is a white to off-white, round, biconvex film coated tablet, debossed with 'E25' on one side and plain on the other.

ACTAMASIN 25 is packed into white opaque PVC/PVdC-Aluminium blister strips containing 10 tablets each. Each cardboard carton contains 30 tablets.

7. Holder of Certificate of Registration

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Registration number: 47/21.12/1118

Date of Revision of Text
08 February 2025

Access to the corresponding Professional Information

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Detailed information on Exemestane 25 is available on the European Medicines Agency web site:

http://www.ema.europa.eu/ or on the Accord Healthcare webpage http://www.accord-healthcare.co.za/