PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

KALMEXAN 50 mg capsules, hard

Etifoxine hydrochloride

Contains sugar:

Each tablet contains 110 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking KALMEXAN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- KALMEXAN 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 KALMEXAN is and what it is used for

KALMEXAN is a tranquilliser used to oppose various emotional and bodily reactions, which accompany anxiety.

2. What you need to know before you take KALMEXAN

Do not take KALMEXAN

- If you are hypersensitive (allergic) to KALMEXAN or to any of the other ingredients of KALMEXAN listed in section 6 of this leaflet.
- If you are in a state of shock.
- If you have severely impaired liver and/or renal function.
- If you suffer from myasthenia gravis (a disease which causes weak muscles).
- If you have had severe liver problems, such as inflammation of the liver (hepatitis) or cytolytic hepatitis, during previous treatment with KALMEXAN.
- If you have had severe skin reactions during previous treatment with KALMEXAN.

Warnings and precautions

Talk to your doctor before taking KALMEXAN:

- If you are at risk of developing liver problems, your doctor will do some tests to check your liver function before starting KALMEXAN and around one month after you start treatment.

You should stop taking the medicine and seek urgent medical attention if you experience the following events during treatment with KALMEXAN:

- Severe skin or allergic reactions (see section 4).
- Jaundice (yellowing of the skin and eyes), vomiting, tiredness, abdominal (belly) pain or swelling, swelling in the legs and ankles, dark urine colour, pale stool colour, or bloody or tar-coloured stool. These could be signs of severe liver problems (see section 4).
- Watery diarrhoea (see section 4).

Talk to your doctor or pharmacist if you experience bleeding from the uterus between menstrual periods (metrorrhagia) when on oral contraceptives during treatment with KALMEXAN.

Other medicines and KALMEXAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

KALMEXAN should not be used together with other central nervous system depressants (medicines that slow downn the brain activity) as the depressant effect may be increased.

Examples of other central nervous system depressants are:

- Medicines related to morphine (painkillers, cough mixtures).
- Antidepressants.
- Hypnotic medicines (medicines used to help you sleep).
- Antihistamines (medicines used to relieve allergic symptoms).
- Medicines used in the treatment of high blood pressure.
- Baclofen (a muscle relaxant).
- Thalidomide (a medicine used to treat a certain type of cancer).

KALMEXAN with food, drink and alcohol

Do not use alcohol or alcohol-containing medicines together with KALMEXAN as alcohol increases the sedating effect of KALMEXAN. This may lead to decreased alertness and may make vehicle driving and machine operations dangerous.

Pregnancy and breastfeeding

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 health care provider for advice before taking KALMEXAN.

KALMEXAN should not be used during pregnancy or breastfeeding.

Driving and using machines

Do not drive or operate any tools or machinery as KALMEXAN causes drowsiness, and impaired

alertness (when used in combination with central nervous system depressants or alcohol/ alcohol containing medicines), and it may hamper your ability to carry out these tasks.

KALMEXAN contains azorubine

Azorubine is an azo colourant which may cause allergic reactions.

KALMEXAN contains lactose

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

3. How to take KALMEXAN

Do not share medicines prescribed for you with any other person.
Always take KALMEXAN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 3 to 4 capsules (150 mg – 200 mg) daily in two to three divided doses. The duration of treatment is usually from a few days to not more than 8 weeks, depending on your doctor’s recommendations.
The capsules should be swallowed with a little water.
Stopping the treatment does not lead to withdrawal.

Your doctor will tell you how long your treatment with KALMEXAN will last. If you have the impression that the effect of KALMEXAN is too strong or too weak, tell your doctor or pharmacist.

If you take more KALMEXAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.
Taking too much KALMEXAN may increase the risk of somnolence (drowsiness).

If you forget to take KALMEXAN

If you forget to take a dose, take it as soon as you remember. However if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

KALMEXAN can have side effects.

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

If any of the following happens, stop taking KALMEXAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Anaphylactic shock (severe flushing, itching, nausea, vomiting, swelling of the mouth and tongue and throat.
- Severe allergic reactions of the skin and face (flushing, rashes, itching, swelling).
- Allergic manifestations such as urticaria (nettle rash, hives) and angioedema (weals, swelling of lips, eyes and tongue).
- Allergic reactions with fever, rash, conjunctivitis (red, swollen eyes).
- Jaundice (yellowing of the skin and eyes), vomiting, tiredness, abdominal (belly) pain - these could be signs of severe liver problem.
- Watery diarrhoea.

These are all very serious side effects. If you have them, you may have had a serious reaction to KALMEXAN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Bleeding between the expected menstrual periods, in women taking oral contraceptive pill.

- Slight drowsiness at the start of treatment and disappearing spontaneously with its continuation.
- Feeling of rapidly progressing obstruction in the throat (Quincke's oedema).

The following side effects may occur, but the frequency is unknown:

- Leukocytoclastic vasculitis (is a skin disorder or condition that is caused by the inflammation of small blood vessels) symptoms include: muscle aches, fever, abdominal pain, cough, joint pain, vomiting, bloody stool, numbness and weakness.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of KALMEXAN.

5. How to store KALMEXAN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store in the original package and do not store in bathrooms.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What KALMEXAN contains

The active substance is etifoxine hydrochloride.

Each capsule contains 50 mg etifoxine hydrochloride.

The other ingredients are fumaric acid, lactose monohydrate and stearic acid. The capsule body and cap contain gelatine, Patent blue, azorubine and titanium dioxide.

What KALMEXAN looks like and contents of the pack

Hard gelatine capsule, with a white-coloured opaque body and blue-coloured opaque cap containing an off-white powder.

Clear PVC/PVDC aluminium blister strips packed in a cardboard carton.

Pack size: 60 capsules.

Holder of certificate of registration

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