SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ANAFRANIL® 10 Tablets

ANAFRANIL® 25 Tablets

ANAFRANIL® SR 75 Divitabs

WHAT ANAFRANIL CONTAINS

The active substance of ANAFRANIL is clomipramine.

ANAFRANIL® 10 Tablets and ANAFRANIL® 25 Tablets contain 10 mg and 25 mg clomipramine hydrochloride respectively.

Each Anafranil 10 mg tablet contains lactose (33,250 mg) and Sucrose (28,230 mg)

Each Anafranil 25 mg tablet contains sucrose (16,500 mg)

ANAFRANIL® SR 75 Divitabs contain 75 mg clomipramine hydrochloride in a slow-release formulation.

The other ingredients are:

ANAFRANIL® 10 Tablets: copovidone (vinylpyrrolidone-vinylacetate copolymer), hypromellose (hydroxypropyl methylcellulose), iron oxide, yellow (E172), lactose monohydrate, macrogol 8000 (polyethylene glycol 8000), magnesium stearate, maize starch, microcrystalline cellulose, povidone (polyvinylpyrrolidone), silicon dioxide, sucrose, talc, titanium dioxide (E171).

ANAFRANIL® 25 Tablets also contain glycerol (85%) and stearic acid.

ANAFRANIL® SR 75 Divitabs: calcium phosphate dibasic, calcium stearate, hypromellose (hydroxypropyl methylcellulose), iron oxide red, macrogolglycerol hydroxystearate (polyoxyl 40 hydrogenated castor oil), polyacrylate dispersion 30%, silicon dioxide, talc, titanium dioxide.

WHAT ANAFRANIL IS USED FOR

ANAFRANIL is used to treat depression and mood disorders. Other psychological conditions that can be treated with ANAFRANIL are obsessions and muscular weakness (cataplexy) associated with recurrent attacks of extreme

sleepiness (narcolepsy) in adults. In children aged above 5 years, ANAFRANIL is used to treat obsessive-compulsive disorders.

BEFORE YOU TAKE ANAFRANIL:

Tell your doctor if you have other medical problems or if you are taking other medicines.

Do not take ANAFRANIL

If you are allergic (hypersensitive) to clomipramine, to any other tricyclic antidepressant, or to any of the other ingredients of ANAFRANIL listed above.

If you are taking certain medicines used to treat depression such as monoamine oxidase inhibitors (MAO inhibitors), selective serotonin reuptake inhibitors (SSRI), or serotonin and noradrenergic reuptake inhibitors (SNaRI).

If you have recently had a heart attack or if you suffer from a serious heart disease.

If the answer to any of these is YES, ANAFRANIL is probably not suitable for you.

If you think you may be allergic, ask your doctor for advice.

Take special care with ANAFRANIL

You should also inform your doctor if you suffer from any of the following:

- If you are thinking about suicide,
- If you have epileptic fits,
- If you have irregular heart beat or other problems with your heart,
- If you have schizophrenia or other mental disorder,
- If you have glaucoma (increased pressure in the eye),
- If you have liver or kidney disease,
- If you have any blood disorder,
- If you have difficulties in passing urine (e.g. due to diseases of the prostate),
- If you have an overactive thyroid gland,
- If you have persisting constipation,

- If you easily faint.

Your doctor will take these conditions into account before and during your treatment with ANAFRANIL.

If any of these apply to you, tell your doctor before you take ANAFRANIL.

ANAFRANIL 10 mg contains Lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ANAFRANIL 10 mg

ANAFRANIL 10 mg and 25 mg contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ANAFRANIL 10 mg and 25 mg

Further safety measures

It is important for your doctor to check your progress regularly to allow dosage adjustments and help reduce side effects. He or she may want to take some blood tests and measure your blood pressure and heart function before and during treatment.

ANAFRANIL may cause dry mouth, which can increase the risk of tooth decay. This means that during long-term treatment you should have regular dental check-ups.

If you wear contact lenses and experience eye irritation, talk to your doctor.

Before you have any kind of surgery or dental treatment, tell the doctor in charge or dentist that you are taking ANAFRANIL.

ANAFRANIL may cause your skin to be more sensitive to sunlight. Stay out of direct sunlight, and wear protective clothing and sunglasses.

Information for families, and caregivers

You should monitor whether your depressed child/patient shows signs of behavioural changes such as unusually anxiety, restlessness, sleeping problems, irritability, aggressiveness, over-excitedness or other unusual changes in behaviour, worsening of depression or thinking about suicide. You should report any such symptoms to the patient's doctor, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms before. You should evaluate the emergence of such symptoms on a day-to-day basis, especially early during antidepressant treatment and when the dose is increased or decreased, since changes may be abrupt.

Symptoms such as these may be associated with an increased risk for suicidal thinking and behaviour and indicate a need for very close monitoring and possibly changes in the medication.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while using ANAFRANIL, please consult your doctor, pharmacist or other healthcare professional for advice.

Pregnant women

Tell your doctor if you are pregnant or breastfeeding. ANAFRANIL should not be used during pregnancy unless specifically prescribed by your doctor.

Your doctor will discuss with you the potential risk of taking ANAFRANIL during pregnancy.

Breastfeeding mothers

The active ingredient of ANAFRANIL passes into the breast milk. Mothers are advised not to breastfeed their babies while taking ANAFRANIL.

Driving and using machines

ANAFRANIL may make some people drowsy or less alert, or it may cause blurred vision. If this happens to you, do not drive, use machinery, or perform other tasks that need full attention. Drinking alcohol may increase drowsiness.

Important information about some of the ingredients of ANAFRANIL

ANAFRANIL 10 mg and 25 mg tablets contain lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose, sucrose), contact your doctor before taking ANAFRANIL 10 mg and 25 mg tablets.

Taking other medicines with ANAFRANIL

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ANAFRANIL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice**.**

Tell your doctor or pharmacist

If you are taking or have recently taken any other medicines.

Remember also those not prescribed by a doctor.

Before starting treatment with ANAFRANIL, tell your doctor or pharmacist about any other medicines that you may be using. Since many medicines interact with ANAFRANIL, it may be necessary to adjust the dosage or stop one of the medicines. It is especially important for your doctor and pharmacist to know if you drink alcohol every day, if you change your smoking habits or if you are taking any of the following:

Medicines used to control blood pressure or heart function, other antidepressants, sedatives, tranquillisers, anticonvulsants (e.g. barbiturates),medicines used to treat asthma or allergies, medicines used to treat Parkinson's disease, thyroid preparations, medicines used to treat ulcer/heartburn such as cimetidine, medicines, used to treat attention deficit/hyperactivity disorder such as methylphenidate, oral contraceptives, oestrogens, medicines used to help the kidneys get rid of salt, and water by increasing the amount of urine produced (diuretics, also known as "water pills"), medicines used to thin blood (anticoagulants).

HOW TO TAKE ANAFRANIL:

Do not share medicines prescribed for you with others.

Follow your doctor's instructions carefully. Do not exceed the recommended dosage.

Your doctor will decide on the most suitable dosage for your particular case. For depression and obsessive-compulsive disorders, the daily dosage is normally between 75 mg and 150 mg. Max daily dose is 250 mg. For muscular weakness (cataplexy) accompanied by extreme sleepiness (narcolepsy), the daily dose is between 25 to 75 mg.

The starting dose for children/adolescent for the treatment of obsessive disorders is 25 mg daily. The max dose is 3 mg/kg or 200 mg, whichever is smaller.

Take ANAFRANIL as directed by your doctor. Do not take more of it, and do not take it more often or for longer than your doctor ordered.

The 75 mg SR divitabs can be halved, but should not be chewed. You can take ANAFRANIL with or without food.

ANAFRANIL and older people

Elderly patients generally need lower doses than young and middle-aged patients. Side effects are more likely to occur in older patients. Your doctor will provide any special information about careful dosage and close observation needed.

ANAFRANIL and children

ANAFRANIL should not be given to children or adolescents unless specifically prescribed by a doctor. Your doctor will provide any special information about careful dosage and close observation needed.

Effects when treatment with ANAFRANIL is stopped

Depression and obsessive-compulsive disorders require long-term treatment with ANAFRANIL. Do not change or stop the treatment without first asking your doctor. Your doctor may want you to reduce the dosage gradually before stopping completely. This is to prevent any worsening of your condition and reduce the risk of withdrawal symptoms such as headache, nausea, and general discomfort.

If you forget to take ANAFRANIL

If you forget to take a dose of ANAFRANIL, take the missed dose as soon as possible and then go back to your normal dosage schedule. If it is almost time for your next dose, skip the missed dose and continue with your normal dosage schedule. If you have any questions about this, ask your doctor.

If you take more ANAFRANIL than you should

If you have accidentally taken too much ANAFRANIL, talk to your doctor straight away. You may require medical attention.

The following symptoms of overdose usually appear within a few hours: severe drowsiness, poor concentration, fast, slow, or irregular heartbeat, restlessness and agitation, loss of muscle coordination and muscle stiffness, shortness of breath, fits, vomiting or fever.

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

POSSIBLE SIDE EFFECTS:

Anafranil can have side effects. These do not normally need medical attention, and may go away during treatment as your body adjusts to the medicine. Ask your doctor if any side effects continue or are bothersome.

Some side effects could be serious

Very common

(likely to affect more than 1 in 10 patients)

Sudden contraction of the muscles, muscle spasms.

Common

(likely to affect between 1 and 10 patients in every 100 patients)

Seeing or hearing things that are not really there, skin reactions (itching or reddening), severe stomach pain, severe loss of appetite, muscle weakness or stiffness, fast heartbeat (racing, pounding), difficulty in speaking, confusion, delirium.

Uncommon

(likely to affect between 1 and 10 patients in every 1000 patients)

Inability to coordinate movement, irregular heartbeat (racing, pounding), and fits.

Very rare

(likely to affect less than 1 in every 10,000 patients)

A nervous system disorder characterized by muscle stiffness, high fever and impaired consciousness; jaundice, frequent infection with fever and sore throat (due to decreased number of white blood cells), allergic reactions with/without coughing and difficulty in breathing, increase pressure in the eye, difficulty in passing urine.

If you experience any of these, tell your doctor straightaway.

Some side effects are very common (likely to affect more than 1 in 10 patients)

Drowsiness, tiredness, dizziness, restlessness, increase in appetite, dry mouth, constipation, blurred vision, trembling, headache, nausea, sweating, weight gain, and sexual difficulties. At the start of treatment, Anafranil may increase your feelings of anxiety, but this effect generally disappears within two weeks.

If any of these affects you severely, tell your doctor.

Some side effects are common (likely to affect between 1 and 10 patients in every 100 patients)

Disorientation, agitation, palpitations, disturbance in attention, sleep disturbances, over-excitedness, aggressiveness, poor memory, yawning, nightmares, numbness or tingling of the extremities, hot flushes, dilated pupils, fall in blood pressure associated with dizziness after abrupt standing or sitting up, vomiting, abdominal disorders, diarrhoea, skin sensitivity to sunlight, worsening depression, swelling of the breasts and discharge of milk, unpleasant taste, ringing in the ears, irritability, feeling detached from a situation (like watching it from afar).

If any of these affects you severely, tell your doctor.

Some side effects are uncommon (likely to affect between 1 and 10 patients in every 1000 patients)

Fever, increase in blood pressure.

If any of these affects you severely, tell your doctor.

Some side effects are very rare (likely to affect less than 1 in every 10,000 patients)

Edema (swollen ankles and/or hands and/or swelling of any other part of the body), hair loss, Patients aged 50 years or older and taking a medicine of this group are more likely to experience bone fractures.

If any of these affects you severely, tell your doctor.

STORAGE AND DISPOSAL OF ANAFRANIL:

For tablets: Store below 30 °C and protect from moisture and light.

For divitabs: Store below 30 °C and protect from moisture.

Keep out of reach and sight of children.

Do not use after the expiry date stated on the label and/or carton.

Return all used ANAFRANIL to your pharmacist.

Do not dispose of unused ANAFRANIL in drains or sewerage system.

PRESENTATION OF ANAFRANIL:

ANAFRANIL is supplied as 10 mg and 25 mg tablets in blister packs of 50, as SR 75 divitabs in blister packs of 30.

IDENTIFICATION OF ANAFRANIL:

ANAFRANIL 10 mg tablets: light yellow, triangular, biconvex, sugar-coated tablets. Apex to base of triangle approximately 5,8 mm. Thickness approximately 3,3 mm.

ANAFRANIL 25 mg tablets: light yellow, sugar-coated, round, biconvex tablets. Diameter approximately 5,6 mm. Thickness approximately 3,5 mm.

ANAFRANIL SR 75 divitabs: rose coloured, film-coated, capsule-shaped, biconvex, divisible tablets scored on the one side. Length approximately 13,2 mm. Width approximately 5,2 mm. Thickness approximately 4,6 mm.

REGISTRATION NUMBER

ANAFRANIL 10 mg Tablets: C/1.2/182

ANAFRANIL 25 mg Tablets: B1532 (Act 101 of 1965)

ANAFRANIL SR 75 Divitabs: W/1.2/140

NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION

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