

Package leaflet: Information for the user

ANAFRANIL[®] 10mg capsules

ANAFRANIL[®] 25mg capsules

ANAFRANIL[®] 50mg capsules

Clomipramine hydrochloride

This medicine will be referred to as Anafranil in this leaflet.

Read all of this information carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Anafranil is and what it is used for

Anafranil contains a medicine called clomipramine hydrochloride. This belongs to a group of medicines called “tricyclic antidepressants”. Anafranil is thought to work either by increasing the amount of chemical “messengers” in the brain or by making their effects last longer.

Anafranil is used to treat depression, obsessions and phobias (irrational fears). It is also used to treat muscular weakness (cataplexy) associated with repeat attacks of extreme sleepiness (narcolepsy) in adults.

2 What you need to know before you take Anafranil

Do not take Anafranil if:

- you are allergic (hypersensitive) to clomipramine or any of the other ingredients of Anafranil (listed in Section 6 below)
- you have ever had a rash or other allergic reaction to any other antidepressants
- you have had a heart attack within the last 3 months
- you have any serious heart disease
- you have any serious liver disease
- you have any other mental illness apart from depression, obsessions or phobias
- you have glaucoma (increased eye pressure)
- you have difficulty in passing urine
- you are pregnant, might become pregnant or are breast-feeding
- you are aged under 18
- you are taking medicines for depression called monoamine oxidase inhibitors (MAOIs), or have taken them within the last 3 weeks.

Do not take Anafranil if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Anafranil.

Take special care with Anafranil

Check with your doctor or pharmacist before taking your medicine if:

- you have epilepsy (fits)
- you have an overactive thyroid gland
- you have a tumour (cancer) of the adrenal gland (such as phaeochromocytoma or neuroblastoma)
- you have low blood pressure
- you wear contact lenses
- you have had severe constipation for a long time
- you find yourself thinking about suicide
- you have had a head injury and suffered brain damage
- you are going to have ECT (electroconvulsive therapy)
- you have an irregular heart beat or other problems with your heart
- you have been diagnosed as having a low level of potassium in your blood (hypokalemia)
- you have schizophrenia or any other mental disorder
- you are elderly

- you have glaucoma(increased pressure in the eye)
- you have liver or kidney disease
- you have any blood disorder
- you have difficulties in passing urine (e.g. due to diseases of the prostate)

- you are easily faint

Information for families, and caregivers

You should monitor whether your depressed child/patient shows signs of behavioral changes such as unusually anxiety, restlessness, sleeping problems, irritability, aggressiveness, over-excitedness or other unusual changes in behavior, 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 behavior and indicate a need for very close monitoring and possibly changes in the medication.

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.

Children or adolescents

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.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Anafranil.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. Anafranil interacts with a large number of medicines.

In particular, do not take Anafranil if you are taking the following:

- medicines for depression called monoamine oxidase inhibitors (MAOIs), or have taken them within the last 3 weeks.

Do not take Anafranil if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Anafranil.

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

- other medicines for depression called SSRIs e.g. fluoxetine, fluvoxamine; tricyclic antidepressants e.g. barbiturates, benzodiazepines
- medicines for other mental illnesses such as schizophrenia or manic depression e.g. thioridazine, lithium
- medicines for high blood pressure
- medicines to treat heart disorders, particularly those used to treat an abnormal heart rhythm
- anticoagulants (blood thinning tablets like warfarin)
- medicines for Parkinson's Disease
- drugs which affect your liver (your doctor will know which these are). They include nicotine and barbiturates
- cold, flu or hayfever drugs such as antihistamines and decongestants
- carbamazepine or phenytoin (for epilepsy)
- cimetidine (for stomach problems)
- methylphenidate (Ritalin) prescribed for children with ADHD
- atropine or similar medicines (including eye drops)
- estrogens (e.g. contraceptive pill or hormone replacement therapy)
- a medicine called terbinafine (used orally to treat skin, hair or nail infections due to fungus)
- drugs used to reduce fat in blood
- grapefruit/grapefruit juice,
- cranberry juice.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Anafranil.

Operations, tests and check-ups

- Tell your doctor or dentist if you are planning to have an operation of any kind, as Anafranil may interact with local or general anaesthetic.
- Your doctor may want to do blood tests and check your heart and liver function while you are taking Anafranil.

- You should go to the dentist regularly if you take Anafranil for a long time. Anafranil can cause a dry mouth which may increase the chance of tooth decay.

Taking Anafranil with food and alcohol

- You should not drink alcohol during your treatment with Anafranil – it may affect you more than usual.
- You can take Anafranil with or without food.

Pregnancy and breast-feeding

Do not take Anafranil if you are pregnant or might become pregnant. Do not take Anafranil if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

If you feel dizzy, tired or have blurred vision when you start to take Anafranil, do not drive or work with machinery until this effect has worn off.

Important information about some of the ingredients of Anafranil

Anafranil capsules contain lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Information for you, your family and caregivers

Information for you

If you are depressed or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to have these thoughts if:

- if you have previously had thoughts about killing or harming yourself
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thought of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away**. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Information for your family and caregivers

The patient should be monitored to see if they show signs of behavioural changes such as unusual anxiety, restlessness, sleeping problems, irritability, aggressiveness, over-excitedness or other unusual changes in behaviour, worsening of depression or thinking about suicide. Any such symptoms should be reported to the patient's doctor, especially if they are severe, start suddenly 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 anti-depressant 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 of suicidal thinking or behaviour and indicate a need for very close monitoring and possible changes in medication.

3 How to take Anafranil

The doctor will tell you how much Anafranil to take and when to take it. Always follow the doctor's instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist.

Taking this medicine

- Swallow your Anafranil capsules whole with a drink of water.
- Keep taking your medicine until your doctor tells you to stop. Do not stop because you do not feel any better. This medicine may take up to 4 weeks to work.
- The medicine may be taken as one dose at night or as smaller doses at intervals during the day.

How much to take

The usual dosages for adults are as follows:

- For depression: 10 mg to 150 mg daily. Severe cases may need even higher doses.
- For obsessions and phobias: 10 mg to 150 mg daily.
- For cataplexy: 10 mg to 75 mg daily.

If you are not sure how much Anafranil to take, ask your doctor or pharmacist.

The elderly

Elderly patients often need a lower dose because they are more likely to experience side effects. Your doctor will tell you about this.

If you take more Anafranil than you should

If you or anyone else, accidentally takes too much Anafranil, tell your doctor or go to your nearest hospital casualty department immediately. Take your medicine pack with you so that people can see what you have taken.

If you forget to take Anafranil

If you miss a dose, take the next dose at the usual time. Then go on as before. DO NOT take a double dose.

If you stop taking Anafranil

Do not stop taking Anafranil suddenly because this may cause withdrawal side effects. If the decision is made by your doctor to discontinue treatment, the dose you will receive will be cut down gradually to prevent the development of withdrawal symptoms. You may get these side effects if you stop taking Anafranil suddenly: feeling or being sick, stomach ache, diarrhoea, headache, difficulty sleeping, nervousness or anxiety. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Anafranil can cause side effects. The side effects are usually mild and disappear as treatment continues.

Some side effects can be serious.

Stop taking Anafranil and tell your doctor immediately if you notice the following very rare symptoms:

- Rash, changes in blood pressure, swelling and increased fluid in tissues, and increased heart rate, difficulty with breathing and collapse. These may be signs of an allergic reaction.
- A high temperature and sweating with rigid muscles and confusion or agitation, or if you experience jerky muscle movements which you can't control. These may be signs of a serious condition known as neuroleptic malignant syndrome.

The side effects listed below have also been reported:

Very common (More than 1 in 10 people have experienced):

Increase in appetite and weight gain.

Headaches, dizziness, nausea, constipation, dry mouth, increased sweating, shaking hands, tremor, difficulty in passing urine, problems with their eyes, feeling tired or sleepy, sexual disturbances, restlessness.

Common (Up to 1 in 10 people have experienced):

Loss of appetite, stomach upset, vomiting, diarrhoea, light headedness when standing up (due to low blood pressure), increased anxiety, agitation, hot flushes, enlarged pupils, speech disturbances, yawning, feeling confused, disorientated or over excited, sleep disturbances, nightmares, hallucinations or thought disturbances, worsening of existing depression, impaired memory and concentration, aggressiveness, disturbances in heart rhythm, increased sensitivity of the skin to sunlight, rash and itching, breast changes, numbness or tingling in the arms and legs, muscle weakness, movement disorder, changes in liver function tests, taste disturbances, tinnitus (ringing in the ears), swelling of the breasts and discharge of milk, irritability, feeling detached from a situation (like watching it from afar).

Uncommon (Up to 1 in 100 people have experienced):

Mood changes including aggression, fits, movement disorders, increased blood pressure, irregular heart rhythm and fever.

Very rare (Up to 1 in 10,000 people have experienced):

Glaucoma, hepatitis causing jaundice (yellowing of the skin or whites of the eyes), and light coloured urine, urinary retention, oedema (generalised swelling), hair loss, blood disorders (which might result in persistent sore throat, fever or frequent infections, unexplained bruising or bruising more easily).

Most of the side effects are mild and may wear off after a few days treatment. If they are severe or last more than a few days, tell your doctor.

Also, if your medicine upsets you in any other way, tell your doctor.

Patients aged 50 years or older and taking medicines of this group are more likely to experience bone fractures.

Children and Adolescents

Anafranil should not be used in the treatment of depressive states, phobias or cataplexy associated with narcolepsy in children and adults under the age of 18 years as long-term safety effects concerning growth, maturation and cognitive and behavioural development of Anafranil in this age group have not yet been demonstrated.

Also patients under 18 may have an increased risk of side effects such as suicidal thoughts, harming themselves and hostility (predominantly aggression, oppositional behaviours and anger) when they take drugs like Anafranil. Despite this, your doctor may prescribe Anafranil for patients under 18 because they decide that this is in their best interests. If your doctor has prescribed Anafranil for you (or your child) and you want to discuss this, please go back to your doctor.

You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Anafranil.

Also reported (frequency not known)

Feeling of inner restlessness and a compelling need to be in constant motion, repetitive, involuntary, purposeless movements, breakdown of muscle, increase in prolactin (a hormone) level in the blood, and serotonin syndrome (syndrome caused due to increase in naturally occurring messenger, serotonin, in brain; manifested by symptoms like agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating and rapid heartbeat), delayed or no ejaculation of semen if you are a male.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace,

IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Anafranil

Keep out of the reach and sight of children.

Do not use Anafranil after the expiry date, which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

The capsules should be protected from heat and moisture.

If your doctor tells you to stop taking Anafranil, please take any unused medicine back to your pharmacist to be destroyed. Do not throw it away with your normal household water or waste. This will help to protect the environment.

6 Further information

What Anafranil contains

- The active substance is clomipramine hydrochloride
- Anafranil Capsules are available in three strengths containing 10, 25 or 50 mg of clomipramine hydrochloride.

The other ingredients are lactose monohydrate, gelatin, magnesium stearate, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172) and

Printing ink Opacode Brown which consists of, Shellac, black iron oxide (E172), red iron oxide (E172) and yellow iron oxide (E172), ammonium hydroxide and propylene glycol (E1520) or alternatively

Printing ink Opacode Brown which consists of titanium dioxide (E171), Shellac (E904), aluminium lakes: yellow (E110), blue (E132) and red (E129), ammonia and propylene glycol

What Anafranil looks like and the contents of the pack

Anafranil 10mg capsules are opaque, hard gelatin capsules with a caramel top and a greyish yellow body. Imprinted on both cap and body is the “GEIGY” logo. They come in packs containing 84 capsules.

Anafranil 25mg capsules are opaque, hard gelatin capsules with a caramel top and a brownish-orange body. Imprinted on both cap and body is the “GEIGY” logo. They come in packs containing 84 capsules.

Anafranil 50mg capsules are opaque, hard gelatine capsules with a caramel top and a light grey body. Imprinted on both cap and body is the “GEIGY” log. They come in packs containing 56 capsules.

Marketing Authorisation Holder and Manufacturer

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