

# Anafranil® 75 mg sustained release tablets

(clomipramine hydrochloride)

## PATIENT INFORMATION LEAFLET

### What you need to know about Anafranil

Your doctor has decided that you need this medicine to help treat your condition.

#### Please read this leaflet carefully before you start to take your medicine. It contains important information.

- Keep the leaflet in a safe place because you may want to read it again.
- If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This medicine is available using the above name but will be referred to as Anafranil in this leaflet.

#### In this leaflet:

1. What Anafranil is and what it is used for
2. Things to consider before you start to take Anafranil
3. How to take Anafranil
4. Possible side effects
5. How to store Anafranil
6. Further information

### 1. WHAT ANAFRANIL IS AND WHAT IT IS USED FOR

- Anafranil is available either as capsules in three different strengths or as sustained release tablets. Clomipramine hydrochloride, the active ingredient in Anafranil, is one of a group of medicines called tricyclic antidepressants. It 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. THINGS TO CONSIDER BEFORE YOU START TO TAKE ANAFRANIL

#### Some people MUST NOT take Anafranil. Talk to your doctor if:

- you think you may be allergic to clomipramine or to any of the other ingredients of Anafranil tablets or capsules. (These are listed in Section 6.)
- 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 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 taking, or within the last 3 weeks have taken, any other medicines for depression, particularly monoamine oxidase inhibitors (MAOIs) or fluoxetine
- you are breast-feeding
- you are aged under 18.

#### You should also ask yourself these questions before taking Anafranil:

- Do you find yourself thinking about suicide?
- Do you have epilepsy (fits)?
- Have you had a head injury and suffered brain damage?
- Are you going to have ECT (electroconvulsive therapy)?
- Do you have irregular heartbeat or other problems with your heart?
- Have you been diagnosed as having a low level of potassium in your blood (hypokalaemia)?
- Do you have kidney disease?
- Do you have schizophrenia or other mental disorders?
- Are you pregnant?
- Do you have a blood disorder?
- Do you have an overactive thyroid gland?
- Have you had severe constipation for a long time?
- Do you have a tumour (cancer) of the adrenal gland (such as pheochromocytoma or neuroblastoma)?
- Do you have low blood pressure?
- Do you wear contact lenses?
- Are you elderly?
- Do you have an inherited intolerance to some sugars such as lactose? The capsules contain lactose.
- Do you have depression or other conditions that are treated with antidepressants? The use of these medicines together with Anafranil can lead to serotonin syndrome, a potentially life-threatening condition (see "Are you taking other medicines?").

If the answer to any of these questions is YES, tell your doctor or pharmacist because Anafranil might not be the right medicine for you.

#### Are you taking other medicines?

Anafranil interacts with a large number of other medicines. Make sure your doctor or pharmacist knows if you are taking any of the following:

- Medicines for depression particularly MAOIs e.g. tranylcypromine, phenelzine; SSRIs e.g. fluoxetine, paroxetine, sertraline, fluvoxamine; tricyclic and tetracyclic antidepressants e.g. amitriptyline, dothiepin, maprotiline, 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
- Beta-blockers e.g. atenolol
- Diuretics e.g. bendroflumethiazide, furosemide
- Anticoagulants (blood thinning tablets like warfarin)
- Medicines for Parkinson's Disease
- Nicotine, e.g. if you smoke or are using nicotine replacement therapy
- Anticonvulsants (used to stop seizures or fits. e.g. barbiturates, phenytoin, carbamazepine or valproate)
- Cold and flu drugs such as antihistamines and decongestants
- Cimetidine, used to treat ulcer/heartburn
- Methylphenidate (Ritalin®) prescribed for children with ADHD
- Rifampicin, used to treat some infections including tuberculosis (TB)
- Quinine (for cramp or malaria treatment)
- Strong painkillers such as morphine or morphine related substances e.g. codeine, dihydrocodeine
- Drugs of abuse including Ecstasy
- Atropine or similar medicines (including eye drops)
- Oestrogens (e.g. contraceptive pill or hormone replacement therapy)
- Medicines, called protease inhibitors, used to treat Human Immunodeficiency Virus e.g. ritonavir, indinavir

3039  
25.06.21[6]

- Medicine called terbinafine used orally to treat skin, hair or nail infections due to fungus
- Colestipol, cholestyramine, used to treat high cholesterol levels
- St. John's wort (*Hypericum perforatum*), a herbal product used to treat depression and other conditions
- Buprenorphine/ opioids (used to treat opioid overdose). These medicines may interact with Anafranil and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

The active ingredient of Anafranil passes into the breast milk. Mothers are advised not to breast-feed their babies while taking Anafranil.

The following symptoms may occur in newborn babies, of mothers that have used Anafranil during pregnancy: breathlessness, tiredness, lack of energy, colic, irritability, dizziness, headache, trembling. If your baby develops any of these symptoms you may need to contact your doctor.

#### Will there be any problems with driving or using machinery?

If you feel dizzy, tired, have blurred vision, have difficulty concentrating, or have other effects such as confusion or disorientation when you start to take Anafranil, do not drive or work with machinery until these effects have worn off.

#### Taking Anafranil with food and drink

Take care when eating grapefruit, or drinking grapefruit juice and cranberry juice as this may increase your chance of experiencing side effects.

#### Other special warnings

- Be careful when drinking alcohol - it may affect you more than usual.
- Tell your doctor or dentist if you are planning to have an operation of any kind, as Anafranil may interact with local or general anaesthetics.
- Your doctor may want to do blood tests and check your heart while you are taking Anafranil.
- Your doctor may want to do blood tests to check your liver function and kidney function.
- You should go to the dentist regularly if you take Anafranil for a long time, because it can cause a dry mouth which may increase the chance of tooth decay.
- If you think your symptoms are getting worse, go and see your doctor.

#### Thoughts of suicide and worsening of your depression or anxiety disorder

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

You may be more likely to think like this:

- 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 thoughts 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 families, and caregivers

You should monitor whether your depressed patient shows 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. You should report any such symptoms 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-day basis, especially 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 for suicidal thinking and behaviour and indicate a need for very close monitoring and possibly 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 his/her 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.

- Swallow your Anafranil tablets 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 usual dosages for adults are as follows:

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

The medicine may be taken as one dose at night, or split into several smaller doses and taken throughout the day. Your doctor will tell you what to do.

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

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 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.

#### What if you forget to take a dose?

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

### **What if you take too many?**

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

### **4. POSSIBLE SIDE EFFECTS**

Anafranil is suitable for most people, but, like all medicines, it can sometimes 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, an increased heart rate, difficulty with breathing and collapse. These may all be the signs of a severe 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 the symptoms of a serious condition known as neuroleptic malignant syndrome.

#### **The side effects listed below have also been reported:**

##### **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.

##### **Up to 1 in 10 people have experienced:**

Loss of appetite, stomach upset, vomiting, diarrhoea, lightheadedness when standing up (due to low blood pressure), increased anxiety, agitation, hot flushes, enlarged pupils, speech disturbance, yawning, feeling confused, disorientated or over-excited, sleep disturbances, nightmares, hallucinations or, thought disturbances, worsening of existing depression, impaired memory and concentration, restlessness, 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.

##### **Up to 1 in 100 people have experienced:**

Mood changes including aggression, fits, movement disorders, increased blood pressure.

##### **Up to 1 in 10,000 people have experienced:**

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

##### **Also reported (frequency unknown):**

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.

##### **Some people have experienced:**

Thoughts of suicide or self-harm (see Section 2 for more information).

An increased risk of bone fractures has been observed in patients taking this type of medicine.

**Most of the side effects are mild and may wear off after a few days treatment. If they are severe or last for more than a few days, tell your doctor. Also, if your medicine upsets you in any other way, tell your doctor.**

### **Children and Adolescents**

Anafranil should not be used in the treatment of depressive states, phobias or cataplexy associated with narcolepsy for children and adolescents 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 (predominately aggression, oppositional behaviours and anger) when they take drugs like Anafranil. Despite this, your doctor may prescribe Anafranil for patients under 18 because he/she decides 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.

### **Reporting of side effects**

If you get any 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 directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE ANAFRANIL**

Store in the original container in order to protect from moisture.

Keep out the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton.

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.

If your medicines show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

### **6. FURTHER INFORMATION**

#### **What Anafranil contains**

Each tablet contains 75 mg clomipramine hydrochloride in a sustained release formulation. The tablets are formulated to release the active ingredient slowly.

The inactive ingredients are colloidal anhydrous silica, calcium hydrogen phosphate, calcium stearate, dispersed acryl polyesters, hypromellose, red iron oxide (E172), hydrogenated castor oil, talc and titanium dioxide (E171)

### **What Anafranil looks like and contents of the pack**

Anafranil are dull, greyish-red, capsule-shaped tablets debossed with 'S' scoreline 'T' on both side.

The tablets come in blister packs containing 28 tablets.

### **Manufacturer and Product Licence Holder**

Manufactured by Pharmalooop, S.L., C/Bolivia, 15. Poligono Industrial Azque, 28806 Alcalá de Henares, Spain.

Alfasigma, S.p.A., Via Pontina, Km 30,400, 00071 Pomezia, Italy.

Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM

PL 20636/3039

Leaflet revision and issue date (Ref) 25.06.21[6]

Anafranil is a trademark of Novartis AG.

**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 020 8423 2111 to obtain the  
leaflet in a format suitable for you.**